

Changes in Extended High Frequency Hearing Following Middle Ear Surgery

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Abstract

Middle ear surgery is frequently performed to eradicate disease and improve hearing. It is reported that thresholds in the extended high frequency (EHF) range (8 – 16 kHz) frequently deteriorate following middle ear surgery, despite improvements to air conduction thresholds and low rates of sensorineural hearing loss to conventional frequency (CF) range (0.25 – 8 kHz) thresholds. Currently, there is a lack of data exploring the nature of post-operative EHF hearing loss, and whether changes are transient or longstanding.

A TEAC HP-F100 bone conduction transducer capable of measuring EHF thresholds was modified and calibrated on 23 normal hearing participants using the real-ear calibration technique. EHF bone conduction data was measured in participants undertaking stapedotomy, ossiculoplasty and tympanoplasty surgeries. Air and bone conduction pure tone audiometry was assessed in four participants from 0.25 - 16 kHz prior to middle ear surgery and at approximately one week, one month and three months following surgery. EHF hearing impairment was evident in all four cases, demonstrating that elements of both sensorineural and conductive hearing loss can occur following middle ear surgeries. EHF sensorineural hearing loss, which partially recovered after three months, was demonstrated in the two stapes participants, whereas conductive hearing loss was more evident in the ossiculoplasty and tympanoplasty participants. Post-operative EHF hearing loss was indicative of potential intra-operative cochlear trauma or changes to the transmission mechanisms of the middle ear.

To assess long-term changes to EHF air conduction thresholds, pure-tone EHF audiometry was performed in two participants who had undertaken stapes surgeries previously, and who had formerly documented EHF hearing impairment. EHF bone conduction thresholds were also established in these two cases for the first time, revealing an EHF hearing loss which contained both sensorineural and conductive components in both cases. Assessing EHF threshold measurements over time in participants undergoing middle ear surgery may be a useful tool to monitor the long-term impacts of surgical factors on hearing outcomes.

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List of Abbreviations

AC	Air conduction
ABG	Air-bone gap
BC	Bone conduction
CI	Confidence interval
CF	Conventional frequencies
CHL	Conductive hearing loss
COM/CSOM	Chronic otitis media/chronic suppurative otitis media
dB	Decibels
dB HL	Decibels hearing level
DPOAE	Distortion product otoacoustic emissions
EAM	External auditory meatus
EHF	Extended high frequency
Hz	Hertz
IHC	Inner hair cell
kHz	Kilohertz
LDV	Laser Doppler vibrometry
OHC	Outer hair cell
PORP	Partial ossicular replacement prosthesis
PTA	Pure-tone audiometry
SNHL	Sensorineural hearing loss
SPL	Sound pressure level
TM	Tympanic membrane
TORP	Total ossicular replacement prosthesis

1.0 Introduction

It has been suggested that utilising audiometry in the extended high-frequency (EHF) range (8 kHz – 20 kHz) may provide a sensitive measure for detecting early trauma to the cochlea in cases of presbycusis (Laukli & Mair, 1985; Osterhammel & Osterhammel, 1979), noise induced hearing loss (Dieroff, 1982; Flottorp, 1973) and ototoxicity (Fausti et al., 1994; Jacobson, Downs, & Fletcher, 1969), among other potential causes of cochlear hearing loss. EHF's have also been monitored in previous research to examine the effects of middle ear surgery on hearing in the EHF region.

Previous research has demonstrated hearing loss can occur in EHF's following several types of middle ear surgery (Babbage, 2015; Doménech and Carulla, 1988; Doménech, Carulla, & Traserra, 1989; Hegewald, Heitman, Wiederhold, Cooper, & Gates, 1989; Laukli & Mair, 1985; Mair & Hallmo, 1994; Mair & Laukli, 1986; Tange & Dreschler, 1990). However, no published studies have conclusively established the cause of hearing loss in the EHF region or whether hearing impairment is predominantly due to middle ear or inner ear damage. In addition, it is still unknown whether the hearing loss that presents following surgery is transient or permanent in nature. Only one previous study to our knowledge, a small pilot study (Babbage, 2015), has examined these issues; however, only four participants were included in the study.

The aim of this current thesis is to expand on the pilot study to determine whether EHF hearing loss following middle ear surgery is the result of inner ear trauma or due to changes to the middle ear. We also intend to show how hearing loss in the EHF region changes over the course of time following surgery. We hope that by finding out this information, preventative surgical techniques and procedures can be applied in future to minimize further damage.

This chapter will provide an introductory description of the anatomy and physiology of the auditory system, along with a basic introduction to hearing assessment and hearing loss. It will be concluded with the aims and hypotheses for the present study.

1.1 Anatomy and physiology of the peripheral hearing system

When investigating the hearing system, it is important to first understand the anatomy and physiology of the various ear structures. Within the peripheral auditory system, there are three main divisions (shown in Figure 1); working laterally to medially is the outer ear, then the middle ear, and finally, the inner ear. Each division will be discussed in further detail.

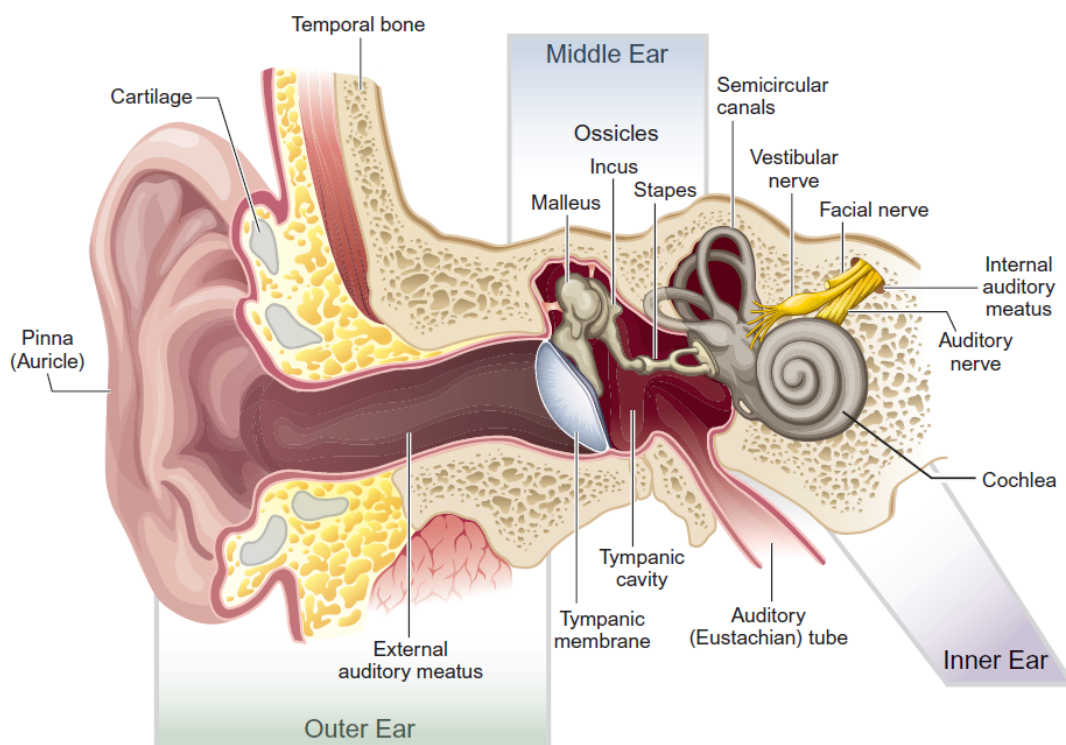


Figure 1. The outer, middle and inner divisions of the ear and the main landmarks within them. Reproduced from Hoit & Weismer (2016).

1.1.1 The outer ear

Auditory information is first collected and transferred through the external ear. The pinna (or auricle) is the visible portion of the ear, which consists of cartilage pieces that are held in place by ligaments (Musiek & Baran, 2007). The cartilage attaches to the temporal bone, protruding away from the head at an angle of approximately 15° to 30° (Rose, 1971;

Yost, 2007). The pinna has a variety of depressions and prominences and acts as a complex resonator of high frequency sounds (Møller, 2013; Musiek & Baran, 2007), and assists in the localization of sound (Blauert, 1983; Hofman & Opstal, 2003). Sound energy collected by the pinna is directed through the external auditory meatus (EAM) (Hoit & Weismer, 2016) towards the tympanic membrane (TM). The EAM functions as an s-shaped “tube”, with the lateral one-third of the EAM cartilaginous, and the remaining medial two-thirds consisting of the bony or osseous portion. The function of the EAM is to act as an acoustic collector and resonator, altering the sound that is then directed towards the TM, which acts as a boundary for the beginning of the middle ear space.

1.1.2 *The middle ear*

The first structure of the middle ear is the eardrum or TM; a thin oval membrane that is concave in shape. The TM is shaped somewhat like a cone (Gelfand, 2016; Musiek & Baran, 2007), with the apex, or umbo, positioned more medially than the rim. The TM is composed of three layers; the outer layer is a continuation of the EAM epidermal lining, while the inner layer is comprised of mucosal lining of the middle ear space. The middle layer, known as the lamina propria, consists of radial and circular fibres and contains collagen, ensuring stiffness and hence allowing for the more efficient conversion of mechanical sound energy into vibrational sound energy (Zemlin, 1998). The fibres are distributed unevenly around the TM (Møller, 2013), with an increase in density toward the periphery of the membrane, referred to as the pars tensa (Musiek & Baran, 2007). Fibres are sparse and less stiff in the upper superior region of the TM, referred to as the pars flaccida, or Schrapnell’s membrane. The annulus is the ring of thickened lamina propria spreading across the entire periphery of the TM with the exception of the upper superior region (Gelfand, 2016).

The middle ear cavity in a normal adult is an irregularly shaped air-filled space enclosed within the temporal bone of the skull, with a volume typically around 2 cm³

(Zemlin, 1998). It is often divided into three sections or chambers: the epitympanum, the upper most chamber above the TM (Seikel, Drumright, & King, 2016), the mesotympanum, consisting of the space between the top and bottom edge of the TM, and the hypotympanum, which sits directly above an important large vein, the jugular bulb (Bonali et al., 2017; Hoit & Weismer, 2016). The lateral boundary of the middle ear cavity is largely formed by the TM, with the space above this in the epitympanum formed by a section of the squamous portion of the temporal bone. Medially, the middle ear cavity is bound by the labyrinthine wall, containing four significant landmarks: the oval and round windows, which provide openings into the inner ear; the promontory space, a protrusion created by the basal turn of the cochlea; and a lateral projection of the canal of the vestibular system (Seikel et al., 2016). The superior wall separates the middle ear cavity from the brain cavity by the tegmen tympani, a thin plate of bone. The posterior wall contains a prominence of the stapedial pyramid, to which the middle ear muscle stapedius originates. The anterior wall provides separation of the middle ear cavity from the internal carotid artery via a small thin bony plate (Zemlin, 1998). Significant landmarks of the anterior wall include one of the middle ear muscles; the tensor tympani, and the opening of the Eustachian or auditory tube, which allows pressure equalization of the middle ear relative to external air, and permits drainage of the middle ear cavity into the nasopharynx space (Gelfand, 2016).

Once sound has been collected by the TM, the sound energy sets the ossicular chain in motion; a series of three small bones which consists of the malleus, incus and the stapes, illustrated in Figure 2 below. The first of the three ossicles, the malleus, weighs around 23 - 37 mg, is approximately 9 mm in length (Musiek & Baran, 2007), and contains a head, a neck and three processes: the manubrium, which attaches to the TM at the point of the umbo, and anterior and lateral processes which provide ligament attachment points (Seikel et al., 2016). The malleus is connected to the second ossicle, the incus, via the double-saddle malleoincudal joint (Gelfand, 2016). The incus weighs around 30 mg and is approximately 7

mm in length, and is comprised of three portions: a body and two processes, or crura; one long and one short. The long process runs parallel to the malleus, ending with a notch termed the lenticular process. The lenticular process is connected to the head of the stapes via the incudostapedial joint (Seikel et al., 2016). The final bone in the ossicular chain, the stapes, is the smallest bone in the human body, weighing around only 2 - 4 mg (Gelfand, 2016). The stapes contains a head, a neck, two crura and a footplate. The head of the stapes, also known as the capitulum, extends to the neck, diverging into two crura. Projecting from the neck of the stapes, the anterior and posterior crura connect to the base of the stapes; the footplate. The footplate is implanted into the oval window of the inner ear (Yost, 2007), supported in place by a ring shaped ligament which surrounds the footplate, termed the annular ligament.

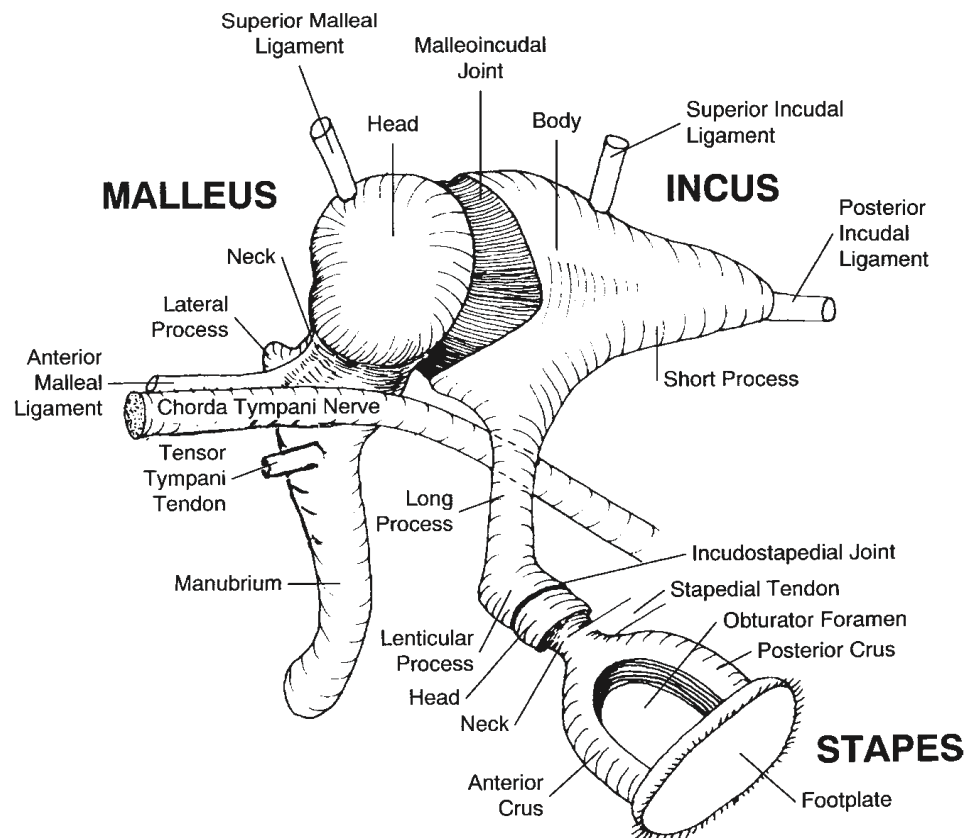


Figure 2. The ossicular chain within the middle ear space. Reproduced from Tos (1995).

In addition to the annular ligament attachment to the inner ear medially and the lateral attachment of the manubrium of the malleus to the TM, the ossicular chain is suspended within the middle ear cavity and supported by several ligaments and the tendons of the two middle ear muscles. There are three ligaments which attach to the malleus: 1) the superior

malleal ligament, running from the tegmen tympani to the head of the malleus, 2) the anterior ligament of the malleus originating from the anterior tympanic wall to the anterior process of the malleus, and 3) the lateral malleal ligament binding to the head of the malleus from the lateral wall (Gelfand, 2016; Seikel et al., 2016). A ligament-like structure termed the posterior ligament of the incus attaches to the short process of the incus, although the structure itself is merely an inconsistent fold of mucous membrane (Zemlin, 1998). There are also two muscles in the tympanic cavity: the tensor tympani, which inserts into the manubrium of the malleus, and contracts to allow the TM to stiffen to reduce the efficiency of vibratory motion (Hoit & Weismer, 2016), and the stapedius muscle, which is attached to the neck of the stapes and likewise with the tensor tympani, allows the ossicular chain to be pulled posteriorly, reducing the amplitude of vibratory energy to the inner ear (Martin & Clark, 2012).

The main function of the middle ear is to transform acoustic energy into vibrational energy. Without the middle ear system, airborne acoustic energy would not be able to be transmitted through to the fluid in the cochlea, as the difference in impedance between the two mediums would cause around 99.99% of sound to be reflected back. Only 0.1% would be converted into vibrational energy of the cochlear fluid, which corresponds to a 30 dB loss of gain (Møller, 2013).

There are two main mechanisms that contribute to the impedance-matching function of the middle ear space. The most significant mechanism is the area difference at the TM relative to the oval window, which produces greater pressure at the oval window compared to the round window of the cochlea, and therefore allows transmission of sound more effectively into the inner ear (Yost, 2007). In addition to this, the lever action of the ossicles also assists in the magnification of pressure to the oval window, but to a smaller extent (Moore, 2012). The most efficiently transmitted frequencies through the middle ear space are the mid-frequencies, of around 500 - 5000 Hz.

1.1.3 *The inner ear*

The inner ear is housed within a bony structure termed the bony labyrinth or otic capsule, and is comprised of two main parts; the vestibular system and the cochlea. The vestibular system consists of three semicircular canals and two otolithic organs, essential for the maintenance of balance (Zemlin, 1998). The cochlea plays a vital role in transforming hydraulic energy into neural signals which are perceived as sound (Hoit & Weismer, 2016).

As illustrated in Figure 3, the cochlea is around 35 mm in length and coils in upon itself approximately two and a half times, giving a snail-like appearance (Hoit & Weismer, 2016). The cochlea is comprised of three chambers or ducts, superiorly to inferiorly; the scala vestibuli, the scala media and the scala tympani. The scala vestibuli contains the oval window opening, attached to the footplate of the stapes. Another opening into the middle ear can be found at the beginning of the scala tympani; the round window, which is covered by a membrane. The scala vestibuli and scala tympani both contain fluid called perilymph, and are connected via the helicotrema; a small passageway at the apex of the cochlea (Martin & Clark, 2012). Between these structures lies the scala media, filled with endolymph fluid. The scala media is wider at the base and narrows as it approaches the apex of the cochlea, and is separated from the scala vestibuli via Reissner's membrane. Along the length of the scala media runs the basilar membrane, a thin membrane which separates the scala tympani from the scala media and which houses the end organ of hearing; the organ of Corti (Møller, 2013). The organ of Corti encompasses sensory hair cells of two types; outer hair cells (OHCs), arranged in rows of three, and inner hair cells (IHCs), arranged in a singular row. The tips of the OHCs are embedded in the tectorial membrane, a gelatinous flap which overlays the hair cells and has an important role in processing acoustic stimuli. The IHCs approximate the tectorial membrane, without making contact (Martin & Clark, 2012).

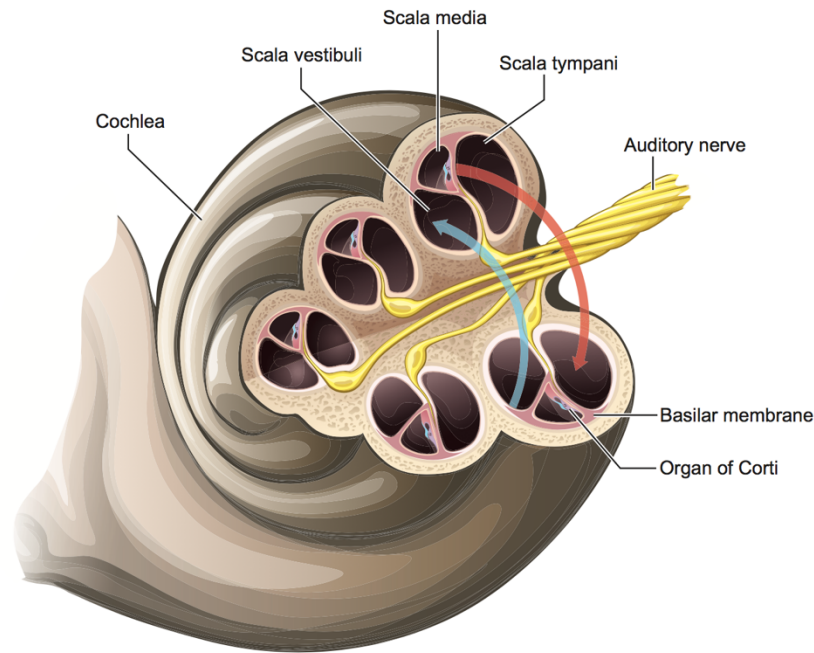


Figure 3. Cross section of the cochlea spiral, demonstrating the three chambers. Reproduced from Hoit & Weismer (2016).

During sound transmission, the inward-outward movement of the stapes causes a displacement of perilymph contained within the scala vestibuli and scala tympani, leading to an exertion of force on the round window (Hoit & Weismer, 2016). The round window functions to prevent pressures between the scala vestibuli and the scala tympani from equalizing. Subsequently, a transverse movement of fluid along the basilar membrane is created called the traveling wave (von Békésy, 1947), whereby maximal vibration occurs at specific points along the basilar membrane where fluid displacement is the greatest. The frequency of the sound signal determines the site of representation on the basilar membrane, with resonance of high frequencies occurring at the stiffness dominated basal end of the cochlea, and low frequency input resonating at the more flexible apical end of the cochlea, as can be seen in Figure 4 (Chan, Kim, & Yoon, 2016; von Békésy, 1947).

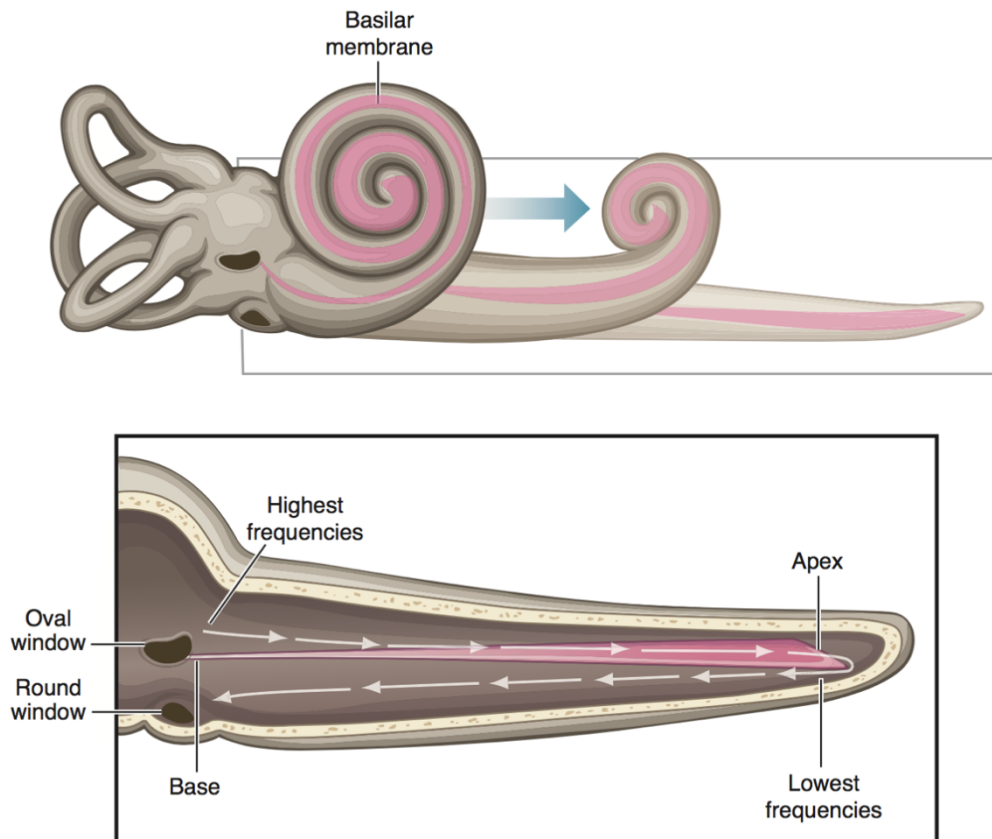


Figure 4. The cochlea chambers hypothetically coiled out. Reproduced from Hoit & Weismer (2016).

The IHCs and OHCs play a significant role in auditory sensation. Excitation of the OHCs is produced as a result of the shearing motion of the tectorial membrane against the tips of the OHCs, facilitated by the slightly altered axes of rotation of the tectorial membrane relative to the basilar membrane from traveling wave movement (Martin & Clark, 2012). The role of the OHCs is to enhance basilar membrane movement, most prominently for softer sounds (Ashmore, 2008) of around 40 - 60 dB SPL. In contrast, the IHCs are activated by displacement of endolymph fluid, which bends and excites the IHCs, transforming hydraulic energy into electrical impulses in the nerve fibres that connect the cochlea to the brain (Hoit & Weismer, 2016). For this reason, the IHCs are termed the afferent component essential for frequency coding, as they send impulses from the peripheral auditory system to the central nervous system via the vestibulocochlear nerve. The central auditory system receives the electrochemical signals at the level of the brainstem, which in turns sends the impulses to the primary auditory cortex in the temporal lobe.

1.2 Hearing assessment

Pure-tone audiometry (PTA) is a diagnostic tool often used to assess the hearing acuity of individuals at a range of frequencies, and is a sensitive measure which is commonly used clinically to detect the type, severity and configuration of hearing loss in each ear. Typically, the conventional frequency (CF) range that is assessed in PTA is 0.25 Hz - 8 kHz, as this range is argued to contain the most important spectral information for speech perception (Fulop, 2011). During PTA, the individual listens and responds to tones presented at a range of frequencies at varying intensities, and the person's threshold (the lowest level to which the person reliably detects sound stimuli) is determined. Thresholds are plotted onto an audiogram in decibels hearing level (dB HL) units as a function of frequency (Hz), to express the hearing sensitivity at different frequencies of an individual, with reference to hearing in a normal hearing healthy ear. A 0 dB HL threshold is quantified as the mean lowest level that is required to stimulate normal hearing at any given frequency, with varying amounts of sound pressure required across frequencies to achieve 0 dB HL (Martin & Clark, 2012). Thresholds that exceed 0 dB HL are therefore considered a deviation from normal hearing, when plotted onto an audiogram.

Traditionally, human hearing acuity is tested via two sound pathways: air conduction (AC) and bone conduction (BC). AC involves the presentation of stimuli through headphones, placed either on top of the ear or in the EAM. AC thresholds give information about the ability of the entire afferent auditory pathway, as the sound has to travel through the outer, middle and inner ear towards the central auditory system. In contrast, BC testing bypasses the outer and middle ear as thresholds are measured using a vibrating device positioned on the mastoid or forehead.

There are three main mechanisms for which BC sound stimuli are transmitted to the cochlea (Homma, Du, Shimizu, & Puria, 2009; Stenfelt, 2011). The first, the external-canal

mechanism, is the transmission of BC sounds through the AC pathway, whereby vibratory energy presented through the BC transducer passes into the cartilaginous portion of the EAM, modifying the sound pressure and stimulating the TM. It has been suggested that this component of BC stimulation plays little role in a normal unoccluded ear, whereby the EAM acts as a high-pass filter, allowing low frequency energy to escape. However, when the EAM is occluded, low frequency energy becomes trapped, enhancing BC thresholds in the lower frequencies by up to 40 dB HL (Stenfelt & Reinfeldt, 2007).

The second mechanism, the inertial-ossicular component, is BC vibration causing the inertia of the ossicles to lag relative to the surrounding bone as it moves in and out of phase with the skull. This is due to the mechanical mass-spring system of the middle ear, whereby the ossicles act as the mass and the TM, ligaments and tendons which suspend the ossicular chain act as the spring. The motion between the surrounding bone and the ossicular chain results in displacement of the stapes relative to the otic capsule, and as with AC stimulation, causes cochlear excitation. The inertial-ossicular component occurs mainly at and above frequencies of 1500 Hz, and works most effectively at 2000 Hz, which is the resonant frequency of the middle ear (Homma et al., 2009).

The inner ear component of BC involves several contributing factors. Alternating compressions, distortions or expansions of the cochlear capsule in response to bone vibrations cause displacement of fluid within the cochlea, initiating a traveling wave on the basilar membrane. One mechanism that assists in the fluid displacement process is the difference in compliance between the oval window and the round window, and the cochlear space within the scala vestibuli and scala tympani. The scala vestibuli contains more space, and hence, when compression of the otic capsule occurs, excess fluid is moved from the scala vestibuli to the scala tympani, where the more compliant round window is situated. Alternatively, when the cochlea expands, the opposite mechanism occurs whereby fluid is forced from the scala tympani to the scala vestibuli, exciting the basilar membrane. Cochlear

compression is more evident in the higher frequencies, most notably limited to 4 kHz and above (Stenfelt, 2011).

Another contributor to the inner ear component of BC hearing is the inertia of inner ear fluids. Along with the cochlea, the round and oval windows are free to vibrate out of phase with skull vibrations, due to inertia. Consequently, cochlear fluid flows between the scala vestibuli and scala tympani, displacing the basilar membrane and hence triggering a traveling wave. This mechanism is more prominent for low frequencies, especially below 1000 Hz (Stenfelt & Goode, 2005).

The presence of alternate pathways for fluid and pressure transmission, including vestibular and cochlear aqueducts, nerve fibres, veins and micro-channels entering the cochlea also contributes to the inner ear component of BC hearing. These pathways allow displaced fluid to both enter and exit the cochlea, acting as a third window to the cochlea which enables the flow of fluid when a pressure gradient occurs over the basilar membrane (Stenfelt, 2011).

In theory, testing BC enables a clinician to differentiate a pathology of the external or middle ear from a pathology affecting the inner ear. However, from examining the three mechanisms of BC hearing, it is apparent that the status of the outer ear or middle ear may influence BC measurements in PTA. Regardless, BC assessment provides a measure to broadly distinguish the site of lesion of hearing loss when comparing to AC thresholds, as changes to BC thresholds in the case of outer or middle ear pathology are typically low compared to the more evident changes in AC thresholds. The following section will continue this discussion by further examining the different types of hearing loss.

1.2.1 Hearing loss

There is significant variability in the type, severity, configuration and cause of hearing loss in individuals. Many factors can cause hearing loss, some of which lead to a permanent

decline in hearing acuity, while other factors result in a treatable, sometimes temporary hearing loss. The following section will briefly summarise the most common types of hearing loss and their causes.

1.2.1.1 *Conductive hearing loss*

When acoustic energy is prevented from being transmitted to the inner ear space, the resultant hearing loss is termed a conductive hearing loss (CHL). Cerumen impaction, foreign bodies and exostoses, among others, are common pathologies of the outer ear that can disrupt the flow of sound energy through the peripheral auditory system (Ballachanda, 2013). Furthermore, certain pathologies can arise in the middle ear space, such as otitis media and otosclerosis (Møller, 2013). A more detailed discussion of these middle ear conditions can be found in Section 1.4.1.

The audiogram for a typical patient with a CHL, an example of which is shown in Figure 5, will usually show elevated AC thresholds, with normal BC thresholds. This is due to the sound stimuli bypassing the blockage in the outer or middle ear, and directly stimulating the unimpaired cochlea during BC testing (Martin & Clark, 2012). The difference between the BC and AC thresholds is defined as the air-bone gap (ABG), the value of which can range from 5 dB HL to a maximum of around 65 dB HL (Rosowski & Relkin, 2001), dependent on the type and severity of the pathological condition. A significant ABG is often considered to be 15 dB HL or more, and certain frequencies are impacted more severely than others depending on the nature of the pathology obstructing the sound transmission. In general, disorders of the middle ear which increase the mass usually affect the higher frequencies; whereas disorders that increase the stiffness in the middle ear generally increase lower frequency hearing thresholds (Stach, 2010). Surgical or medical intervention is often capable of treating CHL, by improving the airborne transmission of sound to the cochlea and therefore reducing the ABG (Moore, 2012).

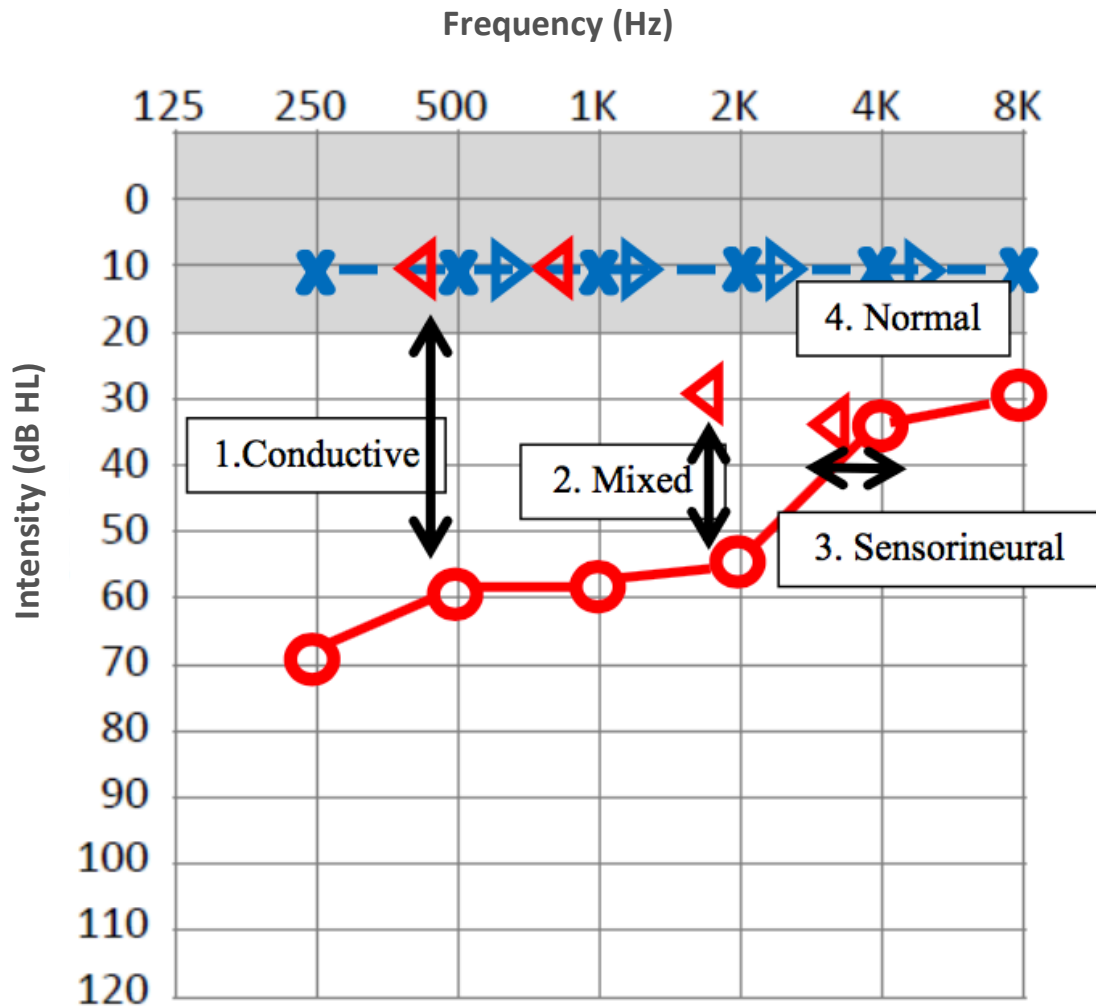


Figure 5. Hearing thresholds plotted onto an audiogram. Conductive hearing loss (1) indicates an air-bone gap of 15 dB HL or more, with bone conduction thresholds less than 20 dB HL. Mixed hearing loss (2) is characterised by an air-bone gap of 15 dB HL and bone conduction thresholds greater than 15 dB HL. Sensorineural hearing loss (3) is defined by a difference of less than 15 dB HL between the air conduction and bone conduction threshold, with both air and bone thresholds exceeding 15 dB HL. Normal hearing (4) is characterised by both air and bone conduction thresholds at 15 dB HL or below, with no difference between air and bone conduction of 15 dB HL or more.

1.2.1.2 *Sensorineural hearing loss*

Sensorineural hearing loss (SNHL), results from damage to the cochlea or, less often, the auditory nerve or higher centres in the auditory pathway (Moore, 2012). Many factors may cause SNHL, including presbycusis, exposure to loud noise, ototoxicity, diseases and infections, trauma or genetic factors (Wong & Ryan, 2015; Yost, 2007). In most cases of SNHL, damage to the OHCs and/or the IHCs is evident, affecting the mechano-electrical

transduction process that strongly contributes to the conversion of mechanical energy into neural impulses (Wong & Ryan, 2015; Zemlin, 1998).

The audiogram of a person with SNHL, exemplified in Figure 5, will have elevated AC thresholds, with BC thresholds which match the level of AC elevation to within +/- 10 dB HL. Increases in thresholds may only be present at a select few frequencies, or there may be varying degrees of threshold elevation across all frequencies (Martin & Clark, 2012). The frequencies that are most affected can often give an indication to the site of damage in the cochlea, with high frequency hearing loss characteristically indicating basal damage, and low frequency hearing loss often indicative of damage localized to the apex (Prosen et al., 1990; Schuknecht & Neff, 1952). Currently, SNHL is unable to be reversed medically or surgically (Wong & Ryan, 2015); however may be managed by use of amplification (Moore, 2012).

1.2.1.3 *Mixed hearing loss*

A mixed hearing loss, illustrated again in Figure 5 below, refers to a combination of SNHL and CHL. The audiogram will show both BC and AC thresholds to be elevated, and the ABG between AC and BC thresholds will be equal to or in excess of 15 dB HL. The reason for this is that sound traveling via the BC pathway will be attenuated only by the inner ear damage; whereas sound traveling through the AC pathway will be attenuated by any outer ear, middle ear and inner ear problems (Martin & Clark, 2012).

1.3 Extended high frequency audiometry

Extended high frequency audiometry (EHF) refers to the testing of frequencies higher than the typically tested CF range of 0.25 – 8 kHz. The upper frequency limit of hearing in a healthy human ear is thought to be around 20 kHz (Sakamoto, Sugasawa, Kaga, & Kamio, 1998), with increases above this resulting in an extremely large sound pressure level (SPL) required to reach threshold. Despite some sounds being audible above 16 kHz, typically they are not tested audiometrically, as thresholds at these frequencies often exceed the power

limits of most modern day audiometers (Ashihara, 2007). As a result of this, EHF testing is most commonly performed in the frequency range of 8 kHz – 16 kHz (Ashihara, 2007; Schmuziger, Probst, & Smurzynski, 2004).

1.3.1 Contributions of EHF to auditory performance

Despite what was once thought, many authors have determined that the spectral information of speech is present at frequencies above 8 kHz (Monson, Hunter, & Story, 2012; Monson, Lotto, & Story, 2012; Monson, Lotto, & Ternström, 2011; Moore, Stone, Füllgrabe, Glasberg, & Puria, 2008). Therefore, it has been suggested that extending the bandwidth of amplification into the EHF range can improve speech audibility and recognition, although there has been some debate in the literature regarding this. Boothroyd and Medwetsky (1992) suggested extending the hearing aid bandwidth up to 10 kHz in order to allow access to the lowest frequency prominent spectral peak of the /s/ phoneme, which was revealed to be 8.9 kHz out of five female talkers. Likewise, Levy, Freed, Nilsson, Moore, and Puria (2015) noted that in comparison to a 4 kHz bandwidth, a 10 kHz bandwidth resulted in significant improvements recognising speech in the presence of a spatially separated masker for individuals with normal hearing and also for those with hearing impairment, although the benefit was not as substantial in the hearing impaired individuals. Stelmachowicz, Pittman, Hoover, and Lewis (2001) also found the phonemes /s/ and /z/ were more easily distinguished in children with hearing impairment when the upper limit of the hearing aids were reconfigured to 9 kHz in comparison to lower frequencies. Contradicting these positive findings for the benefit of increasing the bandwidth in amplification, Moore, Füllgrabe, and Stone (2010) found no added benefit extending the bandwidth above 7.5 kHz.

In addition to possible improvements in speech recognition from improved EHF audibility, EHF speech information has been argued to provide a better perceived sound quality (Moore & Tan, 2003), especially in singers (Monson et al., 2011). Other perceived

benefits of EHF information include improved sound and speech localization (Best, Carlile, Jin, & Van Schaik, 2005; Brungart & Simpson, 2009; Gray, 2014; Jin, Best, Carlile, Baer, & Moore, 2002), and an enhanced ability to separate speech from noise (Dubno, Ahlstrom, & Horwitz, 2002).

1.3.2 *Clinical use of EHF audiometry*

EHF audiometry has already been established for use in many clinical settings as it has been demonstrated to be an early indicator of cochlear damage. For instance, it has been well established that measuring EHF's can be a sensitive measure to detect early age-related hearing loss (presbycusis), which typically affects the upper frequencies first and increases with increasing age (Laukli & Mair, 1985; Löppönen, Sorri, & Bloigu, 1991; Northern, Downs, Rudmose, Glorig, & Fletcher, 1972; Osterhammel & Osterhammel, 1979; Rosen, 1964; Schuknecht, 1964; Wiley et al., 1998). This is likely due to the aging process of the cochlea, where typically the basilar end incurs hair cell damage before the apical end, causing a loss of high frequency hearing sensitivity before progressing to the lower frequencies with advancing age (Gacek & Schuknecht, 1969; Wiley et al., 1998). Presbycusis has proven to be problematic when testing the upper frequency limits of hearing. Increasingly large SPL values are required to reach thresholds as the frequency and the age of the individual increases, often resulting in thresholds that cannot be reached at the maximum output of the audiometer at the higher frequencies (Wiley et al., 1998). The benefit of clinical EHF assessment therefore becomes somewhat more limited when testing adults above the age of around 50 years old, compared to younger listeners (Hallmo, Sundby, & Mair, 1994; Osterhammel & Osterhammel, 1979).

EHF audiometry has also been used to detect early damage to the cochlea as a result of noise exposure (Dieroff, 1982; Fausti, Erickson, Frey, & Rappaport, 1981; Fausti, Erickson, Frey, Rappaport, & Schechter, 1981; Flottorp, 1973; Hallmo, Borchgrevink, & Mair, 1995;

Kumar, Upadhyay, Kumar, Kumar, & Singh, 2017; Laukli & Mair, 1985; Mehrparvar et al., 2014; Mehrparvar et al., 2015; Sataloff, 1967; Somma et al., 2008). For example, Mehrparvar et al. (2014) tested the CF range, the EHF range and distortion product otoacoustic emissions (DPOAEs) in a group of men with noise exposure, concluding that the EHF measurement was the most sensitive of the three measures in early detection of hearing loss. This is a clear demonstration to attest to EHF audiometry being utilised as a sensitive, beneficial measure in detecting inner ear changes.

Currently, the most common clinical use for EHF audiometry is in detecting ototoxicity (Fausti et al., 1994; Fausti et al., 1984; Jacobson et al., 1969; Rodríguez Valiente, 2016; Sakamoto, Kaga, & Kamio, 2000; Yu et al., 2014). Chemotherapy drugs such as cisplatin induce hearing loss more often first at frequencies over 8 kHz, due to the progression of damage from the basal region of the cochlea, which over time spreads to the apical end (Fausti et al., 1994). While detecting ototoxicity cannot prevent further hearing loss from occurring, it is useful for signalling when treatment modification is necessary, such as a lowering of dosages or alternative medication. The use of EHF audiometry could potentially provide a similar application during middle ear procedures, to monitor and indicate when surgical techniques should be altered or additional pharmaceutical therapy is warranted, and thus to minimise further damage to the cochlea.

1.4 Middle ear surgery

Thus far, only the anatomy and physiology of a normal healthy human ear has been examined. However, on occasion pathologies within the middle ear can emerge, disrupting the peripheral auditory system. This section will explore common pathologies that arise in the middle ear and the surgical treatment associated to prevent or repair middle ear disease.

1.4.1 *Common middle ear pathologies requiring reconstructive surgery*

1.4.1.1 *Otitis media*

Otitis media can be defined as any infection of the mucosal membrane which lines the middle ear cavity, and is one of the most common categories of middle ear disorders (Adams & Arts, 2014; Martin & Clark, 2012). Chronic otitis media (COM), also known as chronic suppurative otitis media (CSOM), implies longstanding inflammation of the middle ear and involves symptoms of otitis media such as swelling, redness and bleeding. The mucosal lining can fill with excessive amounts of blood, causing superficial cells to break down and fluid to accumulate in the middle ear cavity. Subsequently, compression of small veins and capillaries in the middle ear cavity can result in necrosis of the mucosa or TM, at times to the point of rupturing. If fluid is unable to escape the middle ear cavity, it may eventually result in mastoiditis; invasion or infection into the mastoid of the temporal bone (Adams & Arts, 2014; Fullmer & Sweeney, 2017). Other manifestations of COM include erosion of the ossicles, middle ear granulation tissue, abnormal static middle ear pressure, dysfunction of the Eustachian tube, or cholesteatoma; a condition in which a collection of squamous epithelial cells are present in the middle ear which can lead to retraction pockets or TM perforation (Musiek, 2012; Strunk, Ted, & Lambert, 2014). Due to the possibility of total or partial loss of the TM and ossicles, COM can lead to a CHL of up to 60 – 70 dB (Merchant & Rosowski, 2013).

1.4.1.2 *Ossicular disarticulation or dislocation*

Another form of middle ear disorder that requires reconstructive surgery is disarticulation or dislocation of the ossicular chain. This can arise for a number of reasons, including blunt, penetrating or compressive trauma, barotrauma, congenital abnormalities, surgical intervention, or necrosis secondary to middle ear infections (Martin & Clark, 2012; Musiek, 2012; Diaz, Brodie, & Kamal, 2014). The damage that occurs to the ossicles is

variable and dependent on the cause and severity of the dislocation, often with total or partial dislocation at the malleoincudal and incudostapedial joints. Generally, the hearing loss that occurs as a result of ossicular discontinuity is conductive and does not exceed 60 dB HL (Møller, 2013), although in cases of trauma there may be additional damage to the cochlea, leading to a mixed hearing loss (Castillo & Roland, 2007).

1.4.1.3 Otosclerosis

Otosclerosis, one of the most common causes of adult CHL, is a progressive condition in which bone of the otic capsule is resorbed (Roland, Kutz Jr, & Isaacson, 2014). The stapes footplate can become fixated in the oval window as a result, impairing the efficiency of sound transmission into the cochlea (Musiek, 2012). Otosclerosis is typically bilateral and more common in women, and the age of onset varies but is commonly around the age of 30 (De Souza, Goycoolea, & Sperling, 2014). Generally a CHL is evident asymmetrically, initially primarily affecting the low frequencies of hearing, with progression over time to affect the entire audiometric range (Handzel & McKenna, 2010). BC thresholds are typically normal, however a 2 kHz dip termed “Carhart’s Notch” is often apparent. One study regarded this as a reflection of the resultant change in otic capsule resonance rather than a true indicator of SNHL, as often the dip disappeared after surgical intervention (Roland et al., 2014). However, it too is possible that this dip is caused by the loss of external and middle ear contributions to BC hearing (Carhart, 1971), as the resonant frequency of BC hearing of the ossicular chain is around 2 kHz (Homma et al., 2009). Over time, the otosclerosis can impinge into the cochlea if left untreated, causing a mixed hearing loss which may reach up to 80 – 85 dB HL (Møller, 2013). The middle ear cavity remains unaffected in individuals with otosclerosis, as the TM, malleus, incus, static pressure and mucosa in the middle ear remain healthy. Therefore, individuals with otosclerosis usually have favourable long-term hearing outcomes following surgery, as the main purpose is to overcome the fixation of the stapes footplate (Merchant & Rosowski, 2013).

1.4.2 *Classification of surgical procedures*

There are many surgical procedures used to treat individuals with middle ear pathologies and the exact procedure chosen will be dependent on factors such as the patient's type of middle ear disorder, the severity of the CHL, the anatomical makeup of the individual, and the individual preferences of the surgeon. In the present study, several surgical procedures were utilised to treat CHL. Although each middle ear surgery is unique, those included in this study share a common aim of improving hearing by closing or narrowing the ABG. A brief description of common middle ear surgical procedures will be provided below.

1.4.2.1 *Tympanoplasty*

Tympanoplasty represents a broad category of surgical procedures designed to repair the TM (Strunk, Ted, & Lambert, 2014). In conjunction with this, work within the tympanum such as ossicular chain repair may be performed. There are several types of tympanoplasty surgical techniques, originally based on Wullstein's classification of tympanoplasty surgeries (Wullstein, 1956). Five categories of tympanoplasty were proposed; Types I through V, which differ based on the location and the extent of the middle ear pathology. Myringoplasty is one form of tympanoplasty which refers to a surgical repair of the TM only, synonymous with Type I of Wullstein's classifications. Typically, this procedure is used when there is a perforation of the TM, but a healthy ossicular chain is intact. The remaining types progressively involve more manipulation of other middle ear structures, up to Types IV and V which involve sound protection of the oval window or a newly created window in the labyrinth. Regardless of the tympanoplasty type, a successful procedure is often regarded as one with a narrowing of the ABG to about 5 dB (Wullstein, 1956).

As tympanoplasty is often used alongside ossiculoplasty, for the present study any surgery which involved reconstruction of the ossicular chain was classified as an ossiculoplasty procedure, as discussed further below.

1.4.2.2 Ossiculoplasty

Ossiculoplasty refers to reconstruction to all or part of the ossicular chain, and as mentioned, is often performed alongside tympanoplasty. The primary aim of ossiculoplasty is to reconstruct the sound-conducting mechanism between the TM and the inner ear (Gluth & Dornhoffer, 2014). Common indications for ossiculoplasty surgery include: a fixed ossicular chain; absent malleus, incus or stapes ossicles; and erosion of the incus. Partial or complete removal of the ossicular chain may be indicated where the ossicles are too diseased to function normally, and are often replaced by a range of prostheses (Merchant & Rosowski, 2013). Examples of commonly used prostheses are shown in Figure 6 and include: partial ossicular replacement prosthesis (PORP), positioned between the stapes capitulum and extending to the TM or the manubrium of the malleus; and total ossicular replacement prosthesis (TORP), where a prosthesis is connected from the TM or manubrium of the malleus to the stapes footplate. An alternative to prostheses includes a procedure called stapes columella tympanoplasty; whereby a repaired TM is extended medially to make direct contact with the capitulum of the stapes. Similarly, a Type IV tympanoplasty may be utilised; where the stapes footplate remains intact and a tissue graft is placed to shield the round window from acoustic energy, resulting in a space between the shield and the round window termed the cavum minor (Merchant & Rosowski, 2013).

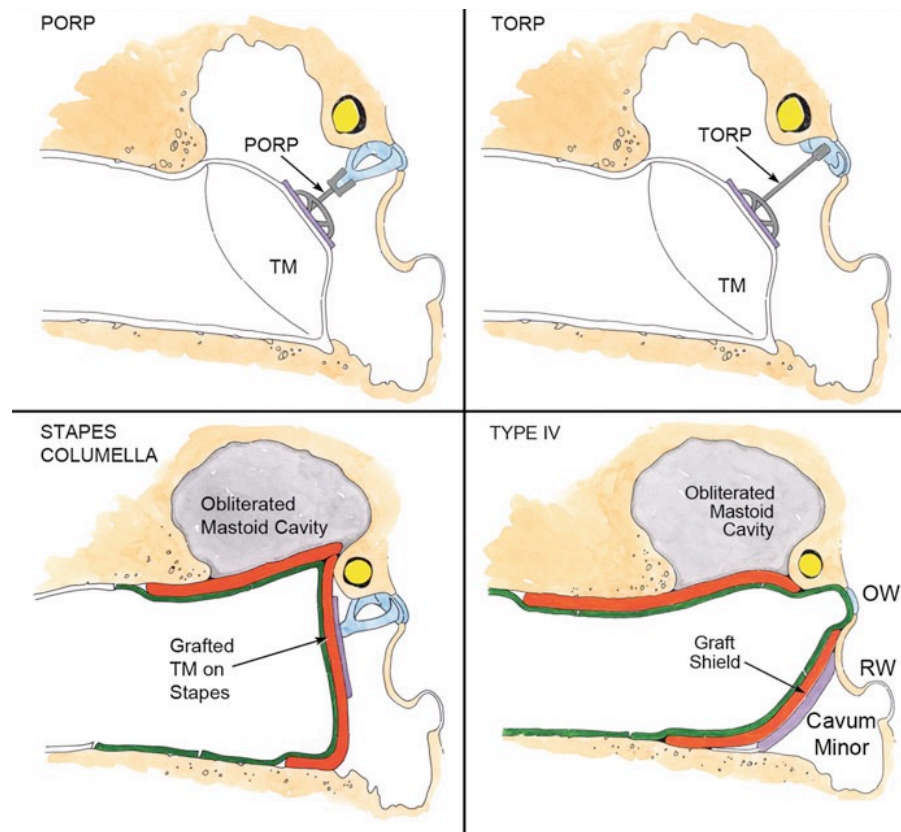


Figure 6. A pictorial representation of the partial ossicular replacement prosthesis (PORP), total ossicular replacement prosthesis (TORP), stapes columella and Type IV tympanoplasty procedures. Reproduced from Merchant and Rosowski (2013) with permission.

1.4.2.3 Stapedectomy and stapedotomy

There are several types of surgeries that are performed on the stapes to treat otosclerosis. A common surgical procedure that is used is stapedectomy, which broadly refers to a group of procedures where the stapes footplate is partially or totally removed and replaced with a prosthesis. Modern day stapedectomy as we know it was revolutionized by Shea (1958), who successfully treated a female with otosclerosis by using a Teflon prosthesis to replace the stapes. Since this time, new materials to replace the stapes and new techniques have been developed allowing partial or total removal of the stapes footplate (Häusler, 2007).

Stapedotomy is a more recent surgical technique which involves drilling to create a small hole into the footplate of the stapes, into which a prosthesis is then inserted (Merchant & Rosowski, 2013; Møller, 2013). Many researchers have demonstrated better speech discrimination scores, hearing stability over time, better high frequency hearing

postoperatively and lower risk of complications, for stapedotomy when contrasted to the stapedectomy technique (Cheng, Agrawal, & Parnes, 2018; De Souza et al., 2014; Møller, 2007; Pedersen, 1987; Pedersen & Elbrond, 1983). Regardless of whether the procedure performed is a stapedectomy or stapedotomy, it has been established that those who typically benefit from the surgery have good preoperative BC levels of around 0 - 25 dB HL, have AC hearing loss of approximately 45 - 65 dB HL and an ABG of least 15 dB (De Souza et al., 2014).

1.5 Effect of middle ear surgery on hearing acuity

Although not the only objective, one of the main motivators for individuals to undertake middle ear surgery is often to improve hearing. Despite frequent improvements in the CF range, it is now clear that there may be a significant deterioration of hearing sensitivity in the EHF range of hearing following middle ear surgery (Babbage, 2015; Babbage, O'Beirne, Bergin, & Bird, 2017; Bird, Babbage, & O'Beirne, 2016; Doménech & Carulla, 1988; Doménech et al., 1989; Hegewald et al., 1989; Mair & Hallmo, 1994; Mair & Laukli, 1986; Laukli & Mair, 1985; Tange & Dreschler, 1990). The effect of middle ear surgery on hearing performance in both the CF range and EHF range will be further discussed in the following sections.

1.5.1 Conventional pure tone audiometry following middle ear surgery

The hearing outcomes of middle ear surgery in the conventional frequency range largely depend on the parameters the researchers use to report patient results (Toner & Smyth, 1993). The frequencies at which authors choose to examine for significant hearing changes will alter the success and complication rates of surgery. Typically, studies report on improvement in AC thresholds and closure of the ABG to indicate surgery success, since these are generally the main aims of surgery.

One of the most commonly reported benefits of reconstructive middle ear surgery in the CF range is the reduction of ABGs, by restoring AC thresholds at, or close to, the value of the BC thresholds. Successful restoration of the conductive mechanism often improves the AC hearing thresholds in the individual at the frequencies of 0.5, 1 and 2 kHz (Babbage, 2015; Harder, Jerlvall, Kylen, & Ekvall, 1982; Kishimoto, Ueda, Uchida, & Sone, 2015; Lee, Hong, Hong, Cho, & Chung, 2008; Salmon, Barriat, Demanez, Magis, & Lefebvre, 2015).

The literature that examines BC changes after stapes surgery tend to use this parameter to assess cochlear damage rather than hearing improvement postoperatively. As a general rule of thumb, studies that assess mean BC threshold changes in the lower frequencies, such as 0.5, 1 and 2 kHz, show lower rates of cochlear injury (Babighian & Albu, 2009; Desai, Aiyer, Pandya, & Nair, 2004; House & Teufert, 2001; Mann, Amedee, Fuerst, & Tabb, 1996; Quaranta, Quaranta, Besozzi, & Fallacara, 2005; Vartiainen & Seppä, 1997), and studies which examine BC threshold changes in the higher frequencies, such as 1, 2 and 4 kHz, reveal higher rates of SNHL (Bergin, 2012; Ginsberg, Hoffman, Stinziano, & White, 1978; Kylén, Arlinger, & Bergholtz, 1977; Persson, Harder, & Magnuson, 1997; Ragheb, Gantz, & McCabe, 1987; Ramsay, Karkkainen, & Palva, 1997). Of all of the frequencies in the CF range, the frequency with the least likelihood to improve following surgery is 4 kHz, which has been hypothesized as being the most susceptible to cochlear trauma (Aslam, 2010; Babbage, 2015; Babbage et al., 2017; Bergin, 2012; Palva, 1973; Persson et al., 1997; Ragheb et al., 1987). Therefore, differences in reporting may not capture the entirety of cochlear or middle ear damage, particularly if there is a small but significant change.

Another factor which influences success and complication rates in the literature is the threshold level that was required to be reached to be classified as a significant SNHL. Studies with high thresholds, such as a 30 dB HL or more threshold changes (Kamal, 1996; Lippert et al., 2001; Mann et al., 1996; Paulose, Kumar, & Sonkhya, 2018), generally show lower rates of post-operative SNHL. For example, the recent research by Paulose et al. (2018) revealed

an incidence rate of only 3% in 100 cases of patients undergoing tympanomastoid surgery, however the criteria to define SNHL was a 30 dB HL change in thresholds at 3 consecutive BC frequencies. Using a high threshold to define SNHL, such as 30 dB HL as opposed to the lower threshold of 5 dB HL, could be insensitive to potentially smaller, but still clinically significant threshold changes. On the other hand, studies that use lower thresholds often exhibit much higher incidence rates. An example of this was demonstrated by Bergin (2012), who performed a retrospective study to assess postoperative SNHL rates, defined by a BC change of more than 10 dB HL postoperatively at 4 Hz. There were 834 patients that were assessed in the study, with 8.3% exhibiting a post-operative SNHL.

Having considered reporting differences to quantify hearing loss, it is not surprising that incidence rates of SNHL following middle ear surgery are incredibly variable in the literature, ranging from around 0.6 – 16.7% (Bergin, 2012; Paulose et al., 2018). Such large variability in incidence rates could be due to a number of other factors besides from those aforementioned, such as the surgery that was performed and the experience of the operating surgeon (Bergin, 2012; Paulose et al., 2018; Toner & Smyth, 1993). Regardless of the incident rates that are reported, it has been well established that SNHL is indeed an identified risk of middle ear surgery. It is for this reason that patients are advised of possible complications of surgery, and are required to give informed consent before having the procedure.

1.5.2 *Extended high frequency audiometry following middle ear surgery*

In recent years, EHF audiometry testing has become an increasingly valuable measure in detecting hearing changes following middle ear surgery. The following section will discuss the evidence base surrounding EHF hearing after middle ear surgery.

1.5.2.1 Changes to post-operative air conduction thresholds

EHF monitoring has become a valuable tool clinically to assess changes in hearing following middle ear surgeries. The first study that observed this effect was Laukli and Mair (1985) who used a high frequency audiometer, the Demlar 20K. Laukli and Mair presented three cases of EHF measurement in individuals who had undergone surgical procedures for middle ear pathologies. One individual who had a perforation of the TM demonstrated no improvement to frequencies from 3 – 20 kHz following myringoplasty despite a restoration of hearing thresholds to normal levels below 3 kHz. Another patient who underwent stapes surgery for otosclerosis also demonstrated increased thresholds in the EHF range post-operatively; however, a second individual who had also undergone stapes surgery demonstrated no change in EHF hearing sensitivity following the procedure. It was proposed that damage induced to the cochlea during the surgical procedures was the potential cause of elevated thresholds. While the authors argued that SNHL was most likely the cause of hearing loss, this data should be treated with caution as assessment timing pre- and post-operatively is unknown and BC was not performed in the EHF to determine if the hearing loss contained conductive or sensorineural characteristics. Furthermore, the authors themselves described that hearing loss could have been a result of middle ear impedance changes. Nevertheless, the study provided preliminary evidence for the value of EHF audiometry in assessing changes in hearing thresholds following middle ear surgery.

Following on from this evidence, a study by Mair and Laukli (1986) assessed changes to AC thresholds in the CF range and the EHF range after 28 stapes surgeries and 36 myringoplasty surgeries. A mean threshold elevation was observed at all frequencies from 12 - 16 kHz, with a significantly greater increase documented in the patients who underwent stapes surgery compared to those who underwent myringoplasty. Again, it is unclear whether the EHF hearing loss was conductive or sensorineural, as no BC testing was performed. The timing of assessments following surgery was also not defined in this study, thereby it is

difficult to determine whether effects were longstanding. Nevertheless, the authors theorized that performing EHF audiometry could have the potential to be a sensitive measure for monitoring surgical techniques in procedures involving the middle ear.

A study by Tange and Dreschler (1990) also examined EHF AC hearing thresholds in individuals following various stapes surgeries. EHF thresholds were measured pre-operatively and at three, six and one year following the procedures. It was demonstrated that deterioration in mean post-operative AC thresholds from 10 - 18 kHz was more prominent in the 13 partial stapedectomies, with a mean increase of 11.9 dB SPL. The 40 patients who underwent stapedotomy procedures also demonstrated an increase in EHF hearing thresholds, although the mean loss was only 5.5 dB SPL. The authors reported that the more complex surgical procedure for stapedectomy was likely the origin of deteriorated thresholds relative to the stapedotomy technique, as the likelihood of traumatic contact with the cochlea was increased for stapedectomy as a result of increased oval window manipulations. Regardless, like the Laukli and Mair (1985) and Mair and Laukli (1986) studies, BC thresholds were not obtained, and therefore this theory could not be confirmed.

More recently, Babbage (2015) administered a series of experiments to further investigate the impact of middle ear surgery on inner ear function. In one experiment, the prevalence and patterns of hearing impairment before and following middle ear surgery were explored. The participants of the study included ossiculoplasty, tympanoplasty and stapes surgery patients, who attended pre-operative testing and repeated testing at one week, one month, three months, six months and one year post surgery. AC thresholds were measured in both the CF and EHF ranges. The results demonstrated that EHF hearing loss was commonly evident in the one to three month period post-operatively, with partial recovery over this time. Despite significant improvements in the closure of ABGs and pure-tone average thresholds in the CF range, 50% of stapes surgery patients and 42% of tympanoplasty patients at the one year follow up still had a residual EHF hearing loss. Due to this, Babbage

(2015) argued that surgical factors may impair the conductive mechanism in the early recovery stages of surgery, with long term hearing impairment remaining due to cochlear trauma. Alternatively, it was also proposed that initial hearing impairment could be the result of inner ear injury, with residual hearing loss over time as a result of permanent alterations to the sound transmission through the middle ear space. However, as EHF BC was not assessed, it was difficult to determine if changes in hearing were due to damage to the conductive system or as a result of sensorineural damage to the inner ear, or a mixture of both.

1.5.2.2 Changes to post-operative bone conduction thresholds

To date, there have been few studies that have examined changes in BC thresholds in the EHF range following middle ear surgery. Initial studies to investigate this include the works of Doménech and Carulla (1988), Doménech et al.(1989) and Hegewald et al. (1989), who each measured thresholds up to 20 kHz using an electrical stimulation technique designed to provoke auditory sensations in the cochlea. An Audimax 500 audiometer was used to measure thresholds before and after stapedectomy surgery (Doménech & Carulla, 1988), tympanoplasty surgery (Doménech et al., 1989) and mastoidectomy surgery (Hegewald et al., 1989). A post-operative reduction to hearing sensitivity within the EHF range was shown in all three studies, regardless of the surgical procedure. Although evidence was provided for SNHL as the cause of elevated post-operative EHF thresholds, there were several methodological limitations to the studies which may limit the clinical applicability of the evidence. For instance, the use of masking to evaluate individual cochlear function was absent in all of the studies. In addition to this, there was a lack of clarity in the Doménech and Carulla (1988) and Doménech et al. (1989) studies regarding follow up assessment timing, and hence it cannot be concluded whether EHF hearing loss was temporary or longstanding. Furthermore, the measurement of mean threshold changes in the Hegewald et al. (1989) research may have been an insensitive measure of EHF assessment, due to the limited output

of the audiometer at higher frequencies and hence, the reduced dynamic range of hearing thresholds that could be measured at the upper frequency limits.

Following this study, Mair and Hallmo (1994), investigated EHF thresholds in 22 myringoplasty surgery patients using an electromagnetic Präcitronic KH70 bone conductor, with masking presented to the contralateral ear to give ear-specific information. While EHF AC thresholds deteriorated post-operatively, BC thresholds remained unchanged. The authors hypothesized that post-operative hearing impairment was due to impaired middle ear transmission, as opposed to a SNHL resultant from cochlea trauma. Furthermore, Hallmo and Mair (1996) discovered little change in masked BC thresholds after middle ear procedures involving the use of a drill, although it was unclear what type of middle ear surgery was utilised in this research. A small but significant elevation of 1.4 dB in thresholds from 8 to 16 kHz was determined in the ipsilateral ear only. Again, the authors predicted that the changes to hearing were more likely due to transducer placement difficulties and consequently reduced middle ear transmission, in contrast to cochlear damage.

In order to determine whether the cause of EHF hearing loss following middle ear surgery is sensorineural or conductive, both masked AC and BC thresholds are required. Ideally these should be assessed over several points in time, to establish whether changes in hearing are temporary or permanent. The only study so far to have achieved both of these factors was the pilot study described by Babbage (2015) and Bird et al. (2016). In the study, AC and BC testing was measured in a small number of participants ($N = 4$) at various time points within three months of surgery, to assess changes in hearing following surgeries. Three participants undergoing stapes surgeries, and one participant undergoing ossiculoplasty, had both AC and BC thresholds of the CF range and the EHF range measured pre-operatively and at one to two weeks, one month and three months post-surgery. A TEAC HP-F100 BC vibrator was modified for clinical use to measure the EHF range. Two of the four cases demonstrated post-operative EHF hearing loss, with initial post-operative tests showing both

CHL and SNHL. Recovery of the conductive component was evident after three months following surgery, so that only the sensorineural element remained. The remaining two cases did not show significant changes following middle ear surgery. Although these results provide some insights into the mechanisms of post-operative EHF hearing loss, Babbage (2015) identified several methodological limitations of the study that restrict the conclusions that can be drawn. Firstly, the small sample size of four in this pilot study meant that clear inferences cannot be made that apply to all patients undergoing middle ear surgery, or to draw surgery specific conclusions. Secondly, the reduced dynamic range of the EHF audiometer provided difficulties in distinguishing between pre-operative and post-operative hearing loss in one of the cases. Thirdly, the contralateral ear was not always able to be masked sufficiently, again due to output limitations of the audiometer. This posed a significant challenge clinically, as masking was required to ensure ear-specific information was collected in the contralateral ear, but the high prevalence of CHL in the participant sample at times prevented this.

The results from the pilot study indicate that EHF hearing thresholds, as measured by the modified TEAC HP-F100 BC transducer, may be a sensitive measure of operative trauma to the cochlea (Babbage, 2015; Bird et al., 2016). To further assess the results from the pilot study, changes in EHF hearing will be monitored closely in the early post-operative stages in the present study.

1.5.2.3 Current challenges of EHF audiometry

Despite the clinical value of EHF BC testing in detecting changes in hearing following middle ear surgery, there are numerous challenges in measuring EHF BC thresholds that have been presented in the literature. Arguably, one of the most important limitations of EHF BC audiometry is the difficulty in accessing the transducer required to measure thresholds. Currently, there are no standardised transducers available for testing

EHF audiometry, and the few commercial EHF BC transducers that are available often require modifications of elements such as the coupling force (Popelka, Telukuntla, & Puria, 2010) to ensure appropriateness for clinical use. As larger SPL levels are required to reach threshold in the EHF relative to the CF range (Reuter, Schonfeld, Mansmann, Fischer, & Gross, 1998), many standard devices designed for CF audiometry are not capable of producing the required output. The BC transducer in the current study, the TEAC HP-F100, was marketed as an alternative to headphones for listening to music, for this reason capable of high vibratory output levels in the high frequency range (Popelka et al., 2010). While this was successfully modified for our study and previous other studies (Babbage, 2015; Bird et al., 2016; Popelka et al., 2010) unfortunately the TEAC HP-F100 transducer is no longer sold commercially. Modifications that were made to this transducer are further discussed in Section 2.1.2.1.

Another difficulty in testing BC thresholds for the EHF is the concern regarding the increased risk of standing waves in the EHF range, which have the ability to falsely elevate hearing thresholds. When testing AC, a substantial amount of acoustic energy is reflected back from the TM into the EAM for higher frequencies in contrast to low frequencies (Stinson, 1985). As frequency is increased, the wavelength becomes shorter, exceeding the structural dimensions of the EAM and hence resulting in standing waves. This raises the concerns that the SPL at the TM that is transmitted through to the inner ear is difficult to predict.

There is also currently no recommended, standardised protocol for testing BC in the EHF region. Babbage (2015) developed a protocol using normal, otologically unimpaired participants to calibrate and verify the clinical reliability and validity of the TEAC HP-F100 transducer. As the same equipment was utilised in this current study, the protocols identified in the Babbage (2015) study were employed for consistency, as discussed further in Section 2.1.

The lack of ability to differentiate the true extent of hearing loss also proves to be another challenging area in both AC and BC EHF testing. Due to the difficulties in gaining enough output to reach thresholds, combined with the natural trend of EHF's to deteriorate with age, noise exposure and ototoxicity, as mentioned prior in Section 1.3.2, determining the extent of EHF degradation proves challenging at times. Often these factors such as noise exposure, age and ototoxicity are not able to be controlled for when being measured over a longer period of time, such as one year. Therefore, some natural aging may impact the level that the thresholds would be measured at.

Another concern regarding AC EHF audiometry is the potential for unwanted noise to be present, particularly when testing at 14 and 16 kHz. This finding has been noted by several authors using a variety of different audiometers (Babbage, 2015; Kurakata, Mizunami, Matsushita, & Shiraishi, 2010; Schmuziger, Brechbuehl, & Probst, 2007). Babbage (2015) demonstrated unwanted noise in the output of two GSI-61 audiometers using Sennheiser HDA 200 circumaural headphones, during the presentation of the 14 and 16 kHz tones. A spectral peak was identified at 5.9 kHz when 14 kHz tone was presented. At 16 kHz, both audiometers demonstrated narrow and broad band components of unwanted spectral energy below 2 kHz. While both audiometers exhibited unwanted noise in the outputs, there was variability between the audiometers in the intensity and frequency characteristics of the noise. Babbage's (2015) study confirms the earlier findings of Kurakata et al. (2010) and Schmuziger et al. (2007) who also reported unwanted spectral peaks at lower frequencies. Although the occurrence of unwanted noise in EHF BC transducers has not been directly examined in any prior studies, given that the noise is a property of the audiometer rather than the transducer (Babbage, 2015), it is likely that BC too could be affected by this phenomenon.

Despite some persistent challenges with measuring the BC thresholds in the EHF's, the measurement of high frequency information is certainly still achievable. The clinical utility

of measuring BC EHF thresholds remains valuable, potentially providing benefit in the early detection of cochlear trauma in middle ear surgery. In light of this, the subsequent section provides more detail on the potential causes of EHF during middle ear procedures.

1.6 Potential causes of EHF hearing loss following middle ear surgery

The site of lesion resulting in an EHF hearing loss following middle ear surgery has yet to be determined. It is possible that EHF hearing loss may be a result of either trauma to the inner ear, middle ear anatomy changes, or a combination of both. It is also likely that the type of surgery influences the site of lesion, since each surgery uses different equipment and techniques, and involves manipulation of different middle ear structures depending on the type of pathology. Sections 1.6.1 and 1.6.2 will further discuss the structural changes or operative insults that occur during middle ear surgery, and which have the potential to cause either temporary or permanent CHL or SNHL, most notably in the EHF.

1.6.1 *Causes of cochlear hearing loss*

A possible cause of cochlear hearing loss that has been proposed in the literature is the result of noise exposure in middle ear surgery. It has been well established that equipment utilised in middle ear surgeries such as drills, suctioning equipment, or a combination of the two, have the capability to produce noise levels harmful to the cochlea (Baradaranfar et al., 2015; Dalchow, Hagemeyer, Muenschner, Knecht, & Kameier, 2013; Kylén & Arlinger, 1976; Kylén, Stjernvall, & Arlinger, 1977). Vibratory energy could also pose a risk to not only the ipsilateral cochlea, but also the contralateral ear due to the low transcranial attenuation of BC sounds (Kylén & Arlinger, 1976). Baradaranfar et al. (2015) found that the contralateral, healthy ear in 26 tympanomastoidectomy surgeries had a temporary threshold shift present in PTA and DPOAE measurements following surgery, which was most prominent at frequencies higher than 2000 Hz, and was reversible after 72 hours. Similarly, Kylén, Arlinger, and Bergholtz (1977) also found a temporary threshold shift ranging from 5 – 40

dB HL at 4 and 8 kHz in patients who had drilling as part of their middle ear surgeries. On the other hand, other studies have found no evidence for SNHL following mastoidectomy surgeries involving the use of a drill (Leonettie et al., 2012; Urquhart, McIntosh, & Bodenstein, 1992). Hallmo and Mair (1996) found no change in BC thresholds after three months following middle ear surgeries, however transient hearing loss may have been present before the three month assessment. Additionally, although de Zinis, Cottelli, & Koka (2010) found a statistically significant relationship between drill use and SNHL at 4 kHz, there is little other conclusive evidence to demonstrate a causal link between timing of drill use and post-operative hearing loss (Hegewald et al., 1989).

Another theory which has strong evidence as a cause of SNHL post-operatively is from surgical equipment making direct contact with the ossicles (Banakis Hartl et al., 2017; Gjurić, Schneider, Buhr, Wolf, & Wigand, 1997; Jiang et al., 2007; Paparella, 1962). Previous studies using animal models have been utilised to explore this such as Gjurić et al. (1997), who demonstrated increased electrocochleography thresholds in 15 guinea pigs when drill contact to the incus occurred for approximately 10 seconds. Likewise, Paparella (1962) demonstrated that drill contact to the incus or malleus in cats for 5 – 15 seconds created damage to the organ of Corti most prominent in the OHCs of the basal end of the cochlea, with damage to this section of the cochlea generally manifesting as a high frequency hearing loss. The relationship between hearing loss and trauma to the ossicular chain has also been observed in several studies using human cadavers. Jiang et al. (2007) used Laser Doppler Vibrometry (LDV) in five cadaver ears to measure displacement of the stapes during drilling on the incus, equivalent to noise levels of 93 – 125 dB SPL. The authors argued this intensity was capable of producing acoustic trauma in the cochlea, particularly at higher frequencies whereby vibratory energy was greater than the lower frequencies in cutting burrs. More recently Banakis Hartl et al. (2017) examined intratympanic pressure and stapes velocity levels in seven cadaver ears in response to direct drilling of the short process of the incus.

Similarly to Jiang et al. (2007), results indicated drilling on the ossicular chain resulted in pressure changes comparable to high intensity acoustic stimulation, providing sufficiently high amplitudes to cause potential cochlear injury. The major limitation to both studies was the use of cadaver subjects, which could be susceptible to post-mortem degradation.

Regardless, the combined literature suggest drill contact to the ossicles during middle ear surgery could indeed cause a significant, permanent SNHL. However, given that incidences of accidental drill contact are reportedly rare, it is likely that accidental drilling is not the cause for post-operative EHF hearing loss in most cases.

Another potential cause of cochlear damage from middle ear surgery which has mixed evidence includes the use of lasers as an alternative to drilling (Arnoldner, Schwab, & Lenarz, 2006; Häusler, Schär, Pratisto, Weber, & Frenz, 1999; Jovanovic, Schonfeld, & Scherer, 2004; Somers et al., 2007). Some authors have argued lasers can result in less trauma to the inner ear in procedures for CSOM and stapedotomy than drilling (Kartush and McGee, 1991; Hamilton, 2010), due to reduced contact with middle ear structures. On the other hand, several authors have argued that there may be risks involved with using lasers during middle ear surgery. These risks involve irradiation injury from the laser waveform travelling through the perilymph, and the laser energy thereby being absorbed in the vestibule (Brase et al., 2013; Kamalski, Verdaasdonk, et al., 2014), thermal injury to the cochlea (Brase et al., 2013; Kamalski, Vincent, Wegner, Bittermann, & Grolman, 2014; Kamalski, Wegner, et al., 2014;), and damage to the IHCs as a result of large pressure waves in the labyrinth from bone detachments (Häusler et al., 1999; Kamalski, Verdaasdonk, et al., 2014). Despite these risks, many studies have exhibited that lasers are able to successfully be used in middle ear surgery without causing permanent trauma to the cochlea (Huber, Linder, & Fisch, 2001; Keck, Wiebe, Rettinger, & Riechelmann, 2002; McGee, Diaz-Ordaz, & Kartush, 1993; Schönfeld, Weiming, Hofmann, Jovanovic, & Albers, 2017; Wiet, Kubek, Lemberg, & Byskosh, 1997), nevertheless, the risk is still apparent.

In addition, hydrostatic pressure changes to the inner ear have been suggested by many authors as being a cause of SNHL following middle ear surgery as a consequence of ossicular manipulation (Babighian & Albu, 2009; Hallmo & Mair, 1996; Kylén, Arlinger, Jerlvall, and Harder, 1980; Mair & Laukli, 1986; Økstad, Laukli, & Mair, 1988; Palva, 1973). It has been hypothesized by Schuknecht and Tonndorf (1960) that acoustic trauma can occur as a result of the forces applied to the ossicles during middle ear surgical procedures, which are much greater than the force that is physiologically exerted via the ossicular chain. Furthermore, Schuknecht and Tonndorf (1960) theorized the greater the acceleration of ossicular movement, the greater the force that is transmitted into the inner ear and thereby the higher the risk of cochlear trauma. Although there is no direct evidence to support the theory of ossicular manipulation as a cause of hearing loss, surgical factors such as surgeon experience have been proposed as potentially playing a significant role in causing cochlear damage. For example, Bergin (2012) demonstrated that trainee surgeons exerted higher levels of force to the inner ear compared to more experienced surgeons. Additionally, the change in preference from stapedectomy to stapedotomy procedures provides evidence in favour of reducing force levels to the cochlea. Stapedotomy is thought to reduce the risk of injury to the cochlea due to less manipulation of the stapes footplate, as a smaller portion is removed compared to stapedectomy, and thereby decreasing the amount of force applied at the oval window (Cheng et al., 2018) . With this in consideration, to our knowledge there is only indirect evidence available to support the theory of hydrostatic pressure as a cause of hearing loss, as most studies assume cochlea injury based on hearing outcomes rather than proven cochlear damage.

Other potential causes that have been investigated include aspiration of perilymph causing transient or irreversible SNHL following stapedectomy and stapedotomy procedures. It has been proposed using animal studies that perilymph suctioning can cause rapid, large reductions in endocochlear potentials (Ikeda et al., 2011), which may result in SNHL

regardless of whether cochlear structures are damaged. However, it is unknown whether perilymph aspiration alone has the capability of producing an isolated EHF SNHL hearing loss. Relatedly, perilymph fistulas are also a rare complication of middle ear procedures that are an unlikely but possible cause of SNHL in the EHF. Fistulas can be defined as a disruption of the connection between the inner and middle ear perilymph compartments, due to either disease erosion, trauma or through contact during ear surgery (Jovanovic et al., 2004; Meldrum & Prinsley, 2016). In addition to these two conditions, both perilymph aspiration and fistulas can also result in secondary endolymphatic hydrops; a condition whereby the perilymph and endolymph pressure balance is disturbed, causing transient or permanent SNHL (Ishai, Haplin, McKenna, & Quesnel, 2016; Shea, Ge, & Orchik, 1995). However, typically the low frequencies are affected, and hence EHF hearing loss is not typically manifested from this condition.

1.6.2 *Causes of hearing loss due to middle ear anatomy changes*

Following middle ear procedures, the characteristics of the reconstructed ossicular chain, among other factors, can influence hearing outcomes. For example, it has been reported that modifications to the mass and stiffness properties of the ossicular chain during middle ear surgeries can significantly alter the transmission of sound, although there is mixed evidence to support this. While the middle ear is said to be mass dominated at higher frequencies (Bance, Morris, & van Wijhe, 2007), some authors have found little impact of incus, malleus and stapes mass on hearing outcomes. Hales, Shakir, and Saunders (2007) measured the improvement in average ABGs across all frequencies in the CF range in ossiculoplasty surgeries, and compared the two prosthesis types that differed in weight and design. They found no significant difference between the two prosthesis types at any given frequency, and in addition, the resonant frequency of the middle ear remained unaltered at 2000 Hz. They proposed that factors other than the prosthesis had more of an impact on ABG closure, such as surgical technique and concurrent middle ear disease. Several authors have

agreed with this finding that the mass of ossicular implants have little impact on hearing outcomes (Ho, Battista, & Wiet, 2003; Rosowski & Merchant, 1995), while other studies have demonstrated that increasing the mass of the ossicular chain affects the transmission of sound through the middle ear, particularly at the higher frequencies within the CF range (Bance, 2018; Bance et al., 2007; Gan, Wood, Dyer, & Dormer, 2001; Goode, Killion, Nakamura, & Nishihara, 1994). What does appear to be more apparent in the literature is that studies which assess the mass of the stapes alone tend to show less effect on hearing outcomes at any given frequency relative to studies that have assessed the mass of the incus or malleus (de Bruijn, Tange, & Schler, 1999; Bance et al., 2007; Goode et al., 1994; Rosowski and Merchant, 1995). However, as no study to our knowledge has directly compared alterations in mass components between ossiculoplasty and stapes procedures, it is difficult to draw any conclusions on this.

Unlike the mass characteristics of the middle ear, it is generally agreed that the stiffness of ossicular prostheses do not tend to have a significant impact on sound transmission (Merchant & Rosowski, 2013). However, it has been proposed that the length of a prosthesis could alter tension properties from the TM to the stapes, modifying sound conduction through the middle ear space. Several authors have shown that increasing the length in the prosthesis results in higher tension of the ossicular chain; with best overall vibration achieved using prostheses which create lower tension (Morris, Bance, van Wijhe, Kiefte, & Smith, 2004; Neudert et al., 2016). In general, low frequency transmissions are reduced and high frequencies are improved with higher tension (Nishihara & Goode, 1994). Thus, it is possible that if a low tension prosthesis is utilised in middle ear surgery, EHF thresholds may be affected despite good outcomes in the lower frequencies of the CF range. Although this may be the case, to verify this relationship is difficult, as currently there are no objective tests intraoperatively to assess this factor.

In addition to mass and stiffness alterations of the ossicular chain, reconstruction of the middle ear can modify the natural pattern of ossicular chain movement, and thus has the potential to produce EHF hearing loss. These ossicular pattern movements are highly complex and are not very well understood. It has been proposed that the stapes movement in even a normal, healthy ear consists of a piston-like motion below 2 kHz, becoming more complex with increasing frequency (Decraemer & Khanna, 2004; Gerig et al., 2015; Goode et al., 1994; Chien et al., 2009; Willi, Ferrazzini, & Huber, 2002). Given that ossicular patterns of vibration are clearly complex, one could assume that any ossicular prosthesis could have the potential to disturb normal ossicular motions. It is possible that this could be more distinct in the high frequencies which potentially are at greater susceptibility to disruption than the lower frequencies.

Changes to the volume of the middle ear space could also potentially be a cause of conductive hearing loss following middle ear surgery. Rosowski and Merchant (1995) used a model analyses to predict hearing outcomes following mastoid surgery, revealing that large middle ear volumes had little effect on the impedance of the middle ear. Conversely, they found the opposite to be true when there was a reduction of middle ear space, whereby the impedance value was increased and caused a decrease in sound transmission through the middle ear cavity. While reductions in volume of a factor of four to 1.5 cc were estimated to result in only a small 2 dB ABG below 1 kHz, further reductions to 0.4 cc created larger predicted ABGs of nearly 10 dB HL. Other studies too have demonstrated a very small effect on sound transmission limited to the low frequencies only when middle ear volume is altered (Gyo, Goode, & Miller, 1986; Whittemore, Merchant, & Rosowski, 1998). Moreover, one study found a shift of up to 10 dB HL in the impedance values of high frequency acoustic stimuli in the middle ear of cadaveric ears (Stepp and Voss, 2005). Cho et al. (2007) also found not only reduced AC thresholds immediately following tympanoplasty surgery, but also a slight reduction in average BC thresholds at 2, 3 and 4 kHz. This could have been a

result of a temporary reduction in combined EAM and middle ear volume as a consequence of packing materials, as the elevation in AC and BC thresholds ceased to exist following post-operative removal of the packing. It is possible that the reduction of BC thresholds indicated loss of the external and middle ear components of BC hearing, as discussed in Section 1.2. Although there is no direct evidence to support the theory that EHF hearing thresholds are too affected by reductions to middle ear volume, this certainly provides a plausible theory of why EHF thresholds can be elevated post-operatively, especially in ossiculoplasty procedures.

While many theories have been presented regarding causes of both post-operative SNHL and CHL, these theories are based on predictive models and experimental data from the analysis of the CF range. There appears to be a significant gap in the literature on changes to EHF hearing thresholds following middle ear surgery, which as mentioned in Section 1.5.2.2, may be of particular importance in detecting cochlear trauma and in monitoring surgical factors such as prosthesis characteristics. Furthermore, the relationship between different types of middle ear surgery, such as ossiculoplasty and stapes surgeries, and the potential causes of hearing loss has also yet to be explored. Determining the causes are necessary to employ methods to reduce further damage to the middle ear or inner ear during surgery, and thereby improve long term hearing outcomes.

1.7 Prevention of EHF hearing loss in future surgical procedures

As little is currently known about the properties of EHF hearing impairment due to the historical lack of BC testing data in this range, currently there are few preventative measures that are available surgically to avoid further SNHL. It has been proposed by Babbage (2015) that discovering the cause of EHF could impact the surgical techniques that are used in future procedures. It is possible that if EHF hearing impairment is largely a result of conductive changes, prosthesis and graft types could be evaluated to restore middle ear

function to closer to the normal state. For example, as discussed in Section 1.6.2, the use of a shorter prosthesis could improve tension of the ossicular chain in ossiculoplasty procedures, potentially improving EHF hearing thresholds. Conversely, if EHF hearing loss is indeed due to inner ear trauma, the impact of surgical instruments, manoeuvres and medication could be further evaluated to determine the success of these interventions on preventing injury to the cochlea.

One method that currently looks to be promising, should the cause of EHF hearing loss be mainly sensorineural characteristically, is the use of pharmacological interventions to reduce damage to residual hearing during middle ear surgery, as discussed by Bird and Bergin (2018). Pharmacological agents such as corticosteroids, which have been utilised in animal models and also during human cochlear implant surgeries in the past, could be useful as a preventative mechanism to the cochlea. Previous studies such as Milewski, Dornhoffer, and DeMeester (1995) and Riechelmann, Tholen, Keck, and Rettinger (2000) have examined corticosteroid use during middle ear procedures with mixed results, however it should be noted that these studies measured hearing loss only through conventional PTA in the CFs. Therefore, it is possible that measurement of EHF thresholds could provide evidence for the efficacy of middle ear surgical interventions such as corticosteroids.

1.8 Aims of the current study

This study was designed to investigate changes to AC and BC EHF thresholds following middle ear surgery, to address the origins of post-operative EHF hearing loss. No study as of yet has fully established the cause of hearing loss in the EHF region following middle ear surgery, and discovering the cause could impact how middle ear surgeries are performed in the future.

1.8.1 *Hypotheses*

It was hypothesized based on Babbage's (2015) pilot study that EHF hearing impairment following middle-ear surgery would initially be a mixture of CHL and SNHL, with recovery of the conductive component over time so that the hearing loss that persisted was predominantly sensorineural. It was further hypothesised that the stapes procedures would result in higher rates of postoperative SNHL in the EHF range than ossiculoplasty and tympanoplasty surgeries, given that stapes surgery involves direct manipulation of the stapes footplate and therefore a higher risk of force transmission to the cochlea (Babbage, 2015; Cheng et al., 2018).

2.0 Establishing correction factors for TEAC HP-F100 transducer

Currently, there are no standardised methods or transducer types to measure BC thresholds in the EHF range. In order to address the aim of the current study to establish the components of EHF hearing loss following both stapes and ossiculoplasty surgeries, a calibrated BC vibrator capable of producing the output necessary for the EHF range was required, and a protocol for testing EHF needed to be established to ensure that hearing thresholds in the EHF range were being measured accurately and reliably.

The BC transducer that was utilised in the present study was a modified TEAC HP-F100, first demonstrated as a potential clinically valid method of measuring accurate and reliable hearing thresholds in the EHF range by Popelka et al. (2010). The transducer has magnetostrictive properties, meaning that the output can be relatively large due to the low mass of the plate. Popelka et al. (2010) discussed that, given the convex shape of the TEAC transducer, the traditional method of calibrating BC transducers using an artificial mastoid was not appropriate. To accommodate for this, they measured thresholds behaviourally in a group of nine participants with no conductive pathology. AC measurements were taken using Sennheiser HDA 200 headphones and a GSI-61 audiometer in the frequency range of 8 – 16 kHz. Thresholds were then repeated using the same audiometer but with the TEAC transducer measuring BC, to determine variability between the two transducers. The variation between the two transducers was found to be minimal, and the authors determined it to be to be clinically acceptable.

Following from this, Babbage (2015) obtained calibration values using a modified TEAC HP-F100 transducer through the use of the real-ear calibration technique. Twenty adult participants with normal otoscopic findings and tympanometry values were used to measure AC thresholds from 8 – 16 kHz using the GSI-61 audiometer with Sennheiser HDA 200 circumaural headphones. A custom computer-based audiometer was configured to

measure BC values from 8 – 16 kHz using the TEAC HP-F100 transducer, along with an additional set of AC thresholds. Measurements were repeated a total of three times to assess test-reliability. As the computer based audiometer expressed sound intensity in arbitrary dB units, the data collected from the calibrated GSI-61 audiometer and the custom audiometer were compared to establish correction values to convert the custom audiometer into dB HL units.

In addition, Babbage (2015) also examined the effect of the transducer site of location on threshold reliability. Five participants with symmetrical hearing thresholds in the EHF range had their BC thresholds measured from 8 – 16 kHz with the transducer placed on three different locations: the mastoid process, the zygomatic process, and the forehead. Measurements were repeated three times at each location to determine the most reliable placement for the transducer to be positioned. The zygomatic process was revealed to exhibit the largest variance and least reliability compared to the forehead and mastoid locations. As there were no significant differences in test-retest reliability between the forehead and mastoid, the forehead was chosen as the optimal site for EHF BC testing for practical reasons. This was given that the larger contact area of the TEAC plate, in comparison to the B-71 transducer, may provide patients with discomfort following middle ear surgery due to postoperative wounds on the mastoid, and additionally, may compromise transmission of BC stimuli to the cochlea (Hallmo & Mair, 1996).

Based on the work achieved by Babbage (2015), the aim of this phase of testing was to re-establish correction values using a similar method, to apply to the uncalibrated TEAC HP-F100 transducer for BC testing in the EHF range.

2.1 Method

2.1.1 Participants

For this phase of the study, 23 volunteers were recruited and invited to attend an appointment where they were given an information sheet about the study (Appendix 1a) and a consent form (Appendix 2) prior to testing. Participants included eight males and fifteen females, and ages ranged from 21 to 28 years ($M = 24.22$, $SD = 2.15$). All participants had no significant otologic history and demonstrated normal otoscopic and tympanometry findings. Participants were required to have measurable thresholds at all frequencies from 0.25 - 16 kHz, with the difference between AC stimuli and BC stimuli in the CF range (0.25 – 8 kHz) bilaterally to not exceed 15 dB HL, which was classified as a significant ABG.

2.1.2 Equipment

Assessments were performed in sound treated rooms meeting the standard of the International Organization for Standardization [ISO] 8253-1 (2010) at the University of Canterbury Speech and Hearing Clinics. Tympanometry was performed using a calibrated Clarinet immittance machine (Inventis, Padova, Italy), with a sweep rate of 200 daPa/s and a probe tone of 226 Hz. The same Clarinet was also used to screen acoustic reflexes using a 1000 Hz ipsilateral stimulus.

To assess PTA in the CF range (0.25 – 8 kHz), a calibrated GSI-61 diagnostic audiometer (Grason-Stadler, Eden Prairie, MN) was utilised. AC stimuli were presented using TDH-39 supra-aural headphones (Telephonics Corporation, Farmingdale, NY). BC stimuli (0.5 – 4 kHz) were presented via a Radioear B-71 (Radioear Corporation, New Eagle, PA) BC vibrator, which was placed on the mastoid.

AC stimuli and narrowband masking noise in the EHF range (8 – 16 kHz) were also presented using the calibrated GSI-61 audiometer, via Sennheiser HDA 200 circumaural

headphones (Sennheiser electronic GmbH & Co., Wedemark, Germany). For BC EHF stimuli, computer based custom audiometer software was used, written using LabVIEW 2012 (National Instruments, Austin, TX). The stimuli were presented through a MOTU multi-channel external sound card (MOTU, Cambridge, MA) that was connected to a laptop via USB. EHF BC stimuli were presented via TEAC HP-F100 BC headphones (TEAC, Tokyo, Japan), which had been modified in a previous study for the purpose of audiometric testing (Babbage, 2015). A brief summary of the modifications made to the transducer is described in the following subsection.

2.1.2.1 Modifications to the TEAC HP-F100 bone conductor

As detailed in Babbage (2015), the TEAC HP-F100 bone vibrator, pictured in Figure 7, was originally designed as a product for consumers to listen to music, providing stimulation bilaterally. The vibrator had two transducers; one on each end that were separated by a plastic headband, which was attached to a 6 cm long steel bracket. The large convex shape of each transducer raised concerns that the static coupling force would be inadequate for reliable threshold measurements during testing, as well as increased difficulty in accurately placing the transducer in the correct position.

To address these concerns, the TEAC HP-F100 transducer was modified using an approach discussed in Popelka et al. (2010), whereby the TEAC transducer was connected to a Radioear P-3333 headband to ensure the static coupling force was adequate for consistency and reliability. The yoke of the TEAC transducer was removed and the original steel bracket that the TEAC was connected to was attached to the P-3333 steel headband using three brass screws. To control the angle at which the contact surface of the transducer met the skull, a 12 mm brass screw was inserted at the top of the earphone through a plastic casing, ensuring that the brass screw would rest against the steel bracket. An example of the modified device is shown in Figure 8.

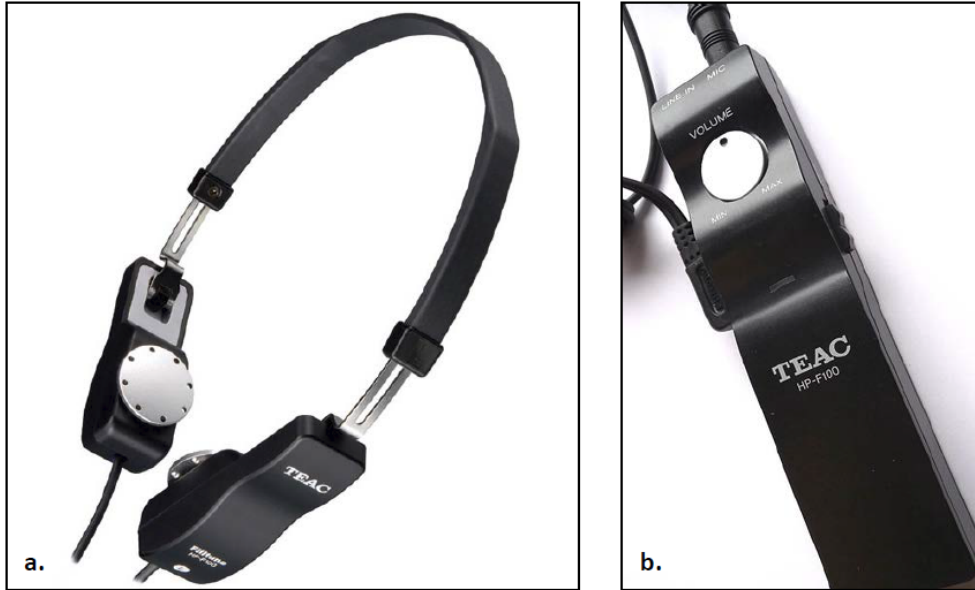


Figure 7. The P-333 headband (a) and a close up of the battery operated power source (b) of the TEAC HP F-100 transducer in the original condition. Reproduced from Babbage (2015).

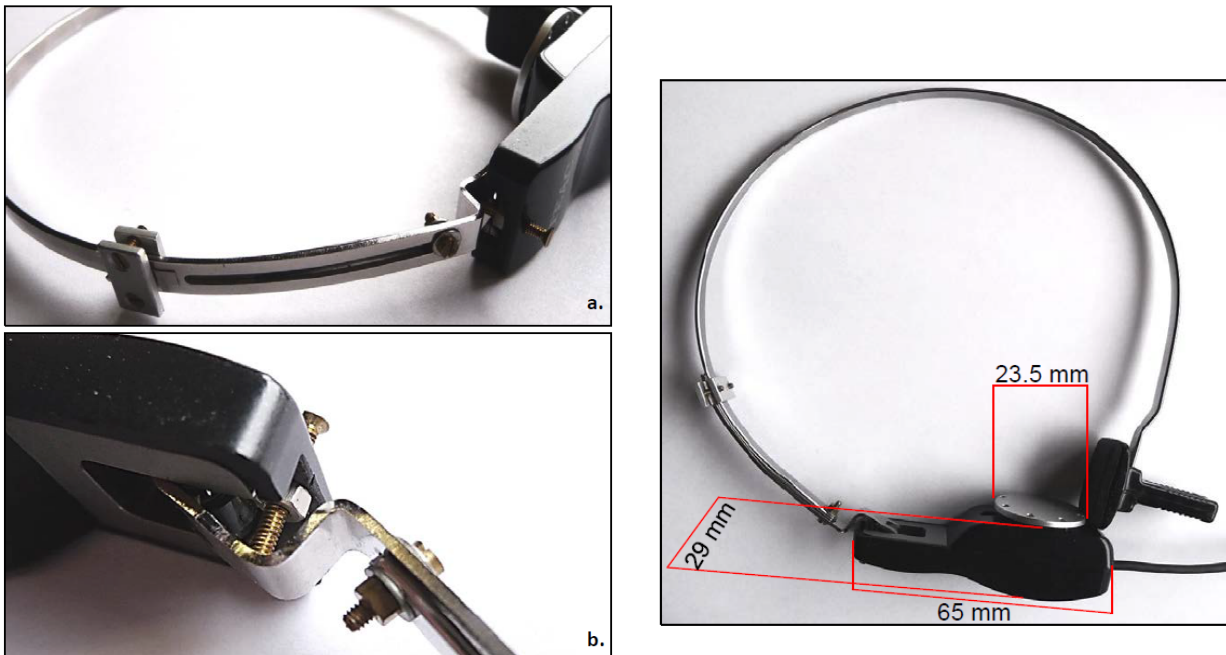


Figure 8. Modifications to the TEAC transducer, including the P-333 headband attachment (a), the metal plates joined with the TEAC transducer via three small screws (b) and the final modified transducer and the dimensions (c). Reproduced from Babbage (2015).

2.1.3 Procedure

Volunteers were examined otoscopically in both ears to exclude abnormalities of the EAM or TM. Tympanometry was then performed and considered normal where the tympanic peak pressure was more than -100 daPa and the admittance value fell in the range of 0.3 to 1.4 cc (Hunter & Shahnaz, 2013). In addition, ipsilateral acoustic reflexes were screened in both ears at 1000 Hz, and participants were considered eligible for the study where acoustic reflexes were present at or below 95 dB HL (Gelfand, Schwander, & Silman, 1990).

AC pure-tone audiometry in the CF range was first assessed in both ears using the GSI-61 audiometer at octave frequencies from 0.25 - 8 kHz, and at inter-octave frequencies where there was a difference of 20 dB HL or more between adjacent octave frequencies. The modified Hughson-Westlake technique using 5 dB HL increments was utilised to obtain hearing thresholds. BC audiometry was assessed via the B-71 bone conductor at octave frequencies from 0.5 - 4 kHz to rule out any significant ABGs, defined as a 15 dB HL or more difference between the AC and BC thresholds for either the left or right ear. Where thresholds exceeded 15 dB HL or more difference at any given frequency up to 4 kHz, masking was applied to the non-test ear using a step masking technique, outlined by Yacullo (1996). Participants were considered to be eligible for the study if they had no significant ABGs at any frequency tested, or had hearing thresholds of 15 dB HL or lower at 4 kHz and below.

If a participant was considered eligible, they were invited to take part in the second part of the study. This involved first bilateral AC testing in the EHF range at 1/6th octave intervals from 8 - 16 kHz, using the GSI-61 audiometer. Participants were required to have measurable thresholds at all frequencies. A step size of 2 dB was utilised since the EHF range contained information of the greatest interest. If thresholds at all test frequencies were

measurable bilaterally within the EHF range, the participant was invited to take part in the final part of the study.

The third stage involved BC testing in the EHF range. The TEAC HP-F100 transducer was placed on the forehead as close to the midline as possible without compromising stability. The Sennheiser HDA 200 circumaural headphones were positioned over the randomly chosen non-test ear for contralateral masking, with the test ear remaining unoccluded. Again, thresholds at all frequencies were measured using a 2 dB step size, and contralateral narrowband masking noise was always applied to the non-test ear to provide ear specific information. The conservative level of 30 dB HL above the non-test ear threshold for the test frequency was selected as the initial masking level, and a step masking procedure outlined by Yacullo (1996) was again utilised.

2.1.4 *Data analysis*

Correction values to convert the soundcard BC thresholds into dB HL units were established by calculating the difference between the mean AC thresholds at each frequency measured using the GSI-61 audiometer and the mean BC thresholds measured using the custom computer audiometer at the same frequency. This was calculated based on the assumption that AC EHF thresholds were equal to BC EHF thresholds, given there were no present ABGs apparent in the CF range of testing and normal otoscopic, tympanometry and ipsilateral acoustic reflex findings. Frequency specific correction factors expressed were subtracted from each uncalibrated BC frequency to convert the measurement into dB HL units.

2.2 Results

2.2.1 GSI-61 AC thresholds

Mean AC thresholds using the GSI-61 audiometer across the CF (0.25 – 8 kHz) and EHF range (8 – 16 kHz) are displayed below in Figure 9. All mean thresholds fell below 10 dB HL, however, there was a large range of thresholds obtained. In general, variance was lower in the CF range, typically with increasing standard deviations with increasing frequency above 8 kHz. The frequency with the largest amount of variance was 16 kHz, with a standard deviation of 16.2 in the right ear.

2.2.2 GSI-61 BC thresholds

Mean BC thresholds and their standard deviations were also calculated for the CF range (0.5 – 4 kHz), as shown in Figure 10. All mean thresholds fell below 10 dB HL. As with AC thresholds, there was a large range of measurements across participants, with the largest amount of variance being at 0.5 kHz, which had a standard deviation of 7.5.

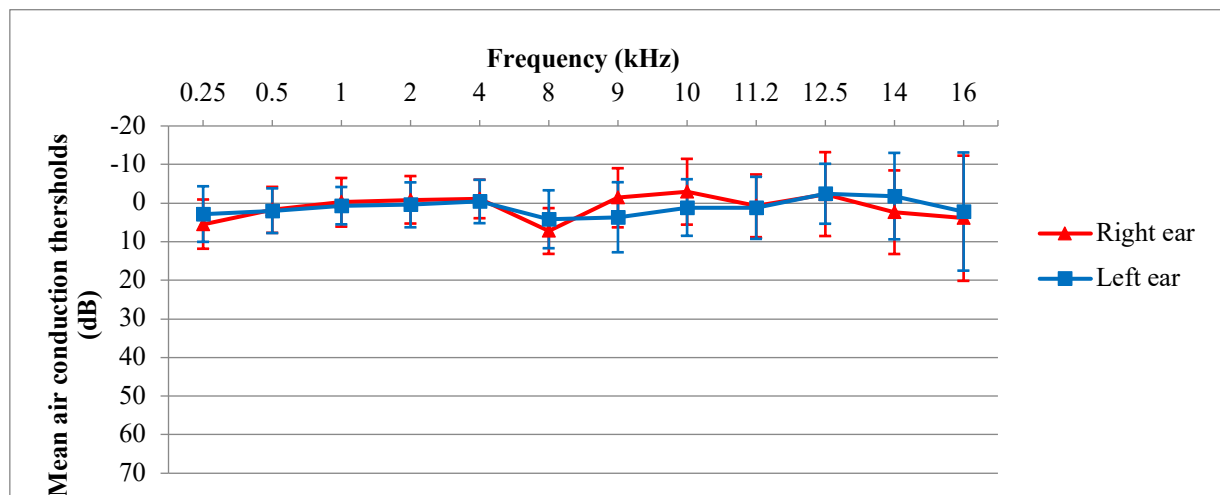


Figure 9. Mean AC thresholds measured for the left and right ear using the GSI-61 audiometer. Error bars show standard deviation values.

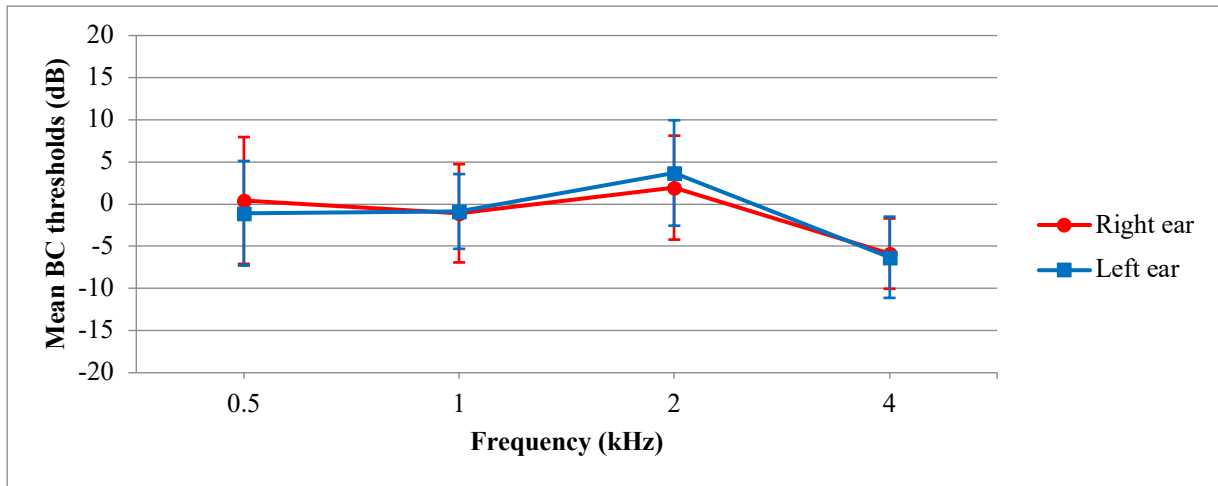


Figure 10. Mean BC thresholds measured for the left and right ear using the GSI-61 audiometer. Error bars show standard deviation values

2.2.3 Differences between GSI-61 AC and BC threshold measurements

Mean differences between AC measurements and BC measurements in the CF range (0.5 – 4 kHz) were calculated for each ear (shown in Figure 11). The majority of mean threshold differences recorded were within ± 5 dB of 0 dB at all frequencies, with the exception of 4 kHz in the left ear, which displayed an average difference of 5.9 dB between AC and BC thresholds. This indicates no significant air-bone gaps in the CF range, and therefore was considered adequate to commence EHF testing operating on the assumption that EHF AC and BC thresholds would be equal.

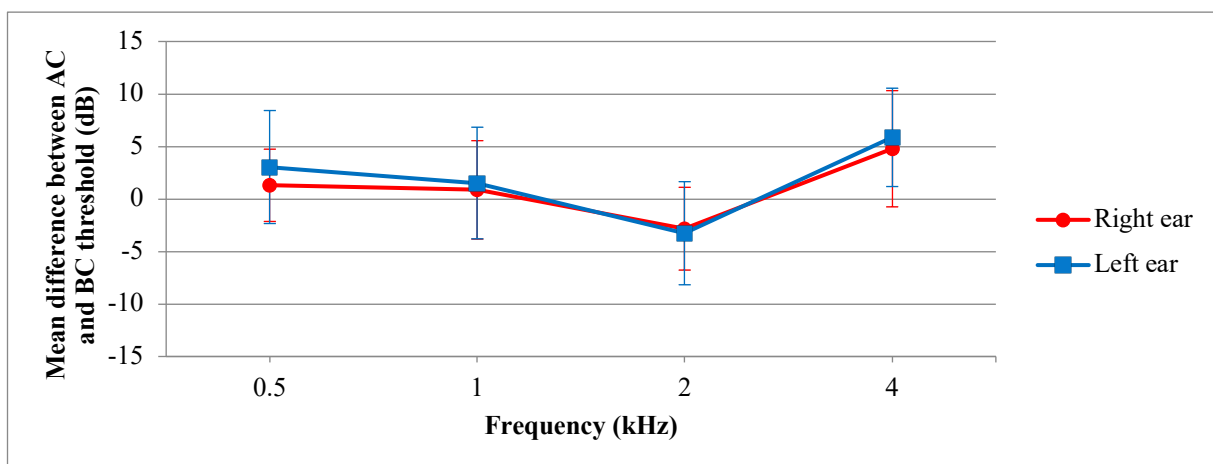


Figure 11. Mean difference between AC and BC thresholds for both the left and right ears obtained using the same GSI-61 audiometer. Positive values indicate better BC thresholds than AC threshold, whereas negative values indicate better AC thresholds. Error bars show standard deviations.

2.2.4 *EHF thresholds*

Figure 12 displays mean AC and BC thresholds in the EHF range (8 – 16 kHz) in the test ear measured using the GSI-61 audiometer and the soundcard audiometer, respectively. For AC measurements, all mean thresholds were below 10 dB HL, and the mean threshold at any given frequency was within +/- 5 dB of 0 dB. The mean value for the uncalibrated BC thresholds using the custom computer audiometer varied between 16.4 dB and 41.2 dB, typically growing larger with increasing frequency towards 16 kHz. For both AC and BC measurements collected, standard deviations typically became more elevated with increasing frequency, to a maximum of 16.6 dB at 16 kHz for AC thresholds using the GSI-61 audiometer and 14.2 dB at 16 kHz for BC thresholds using the custom audiometer.

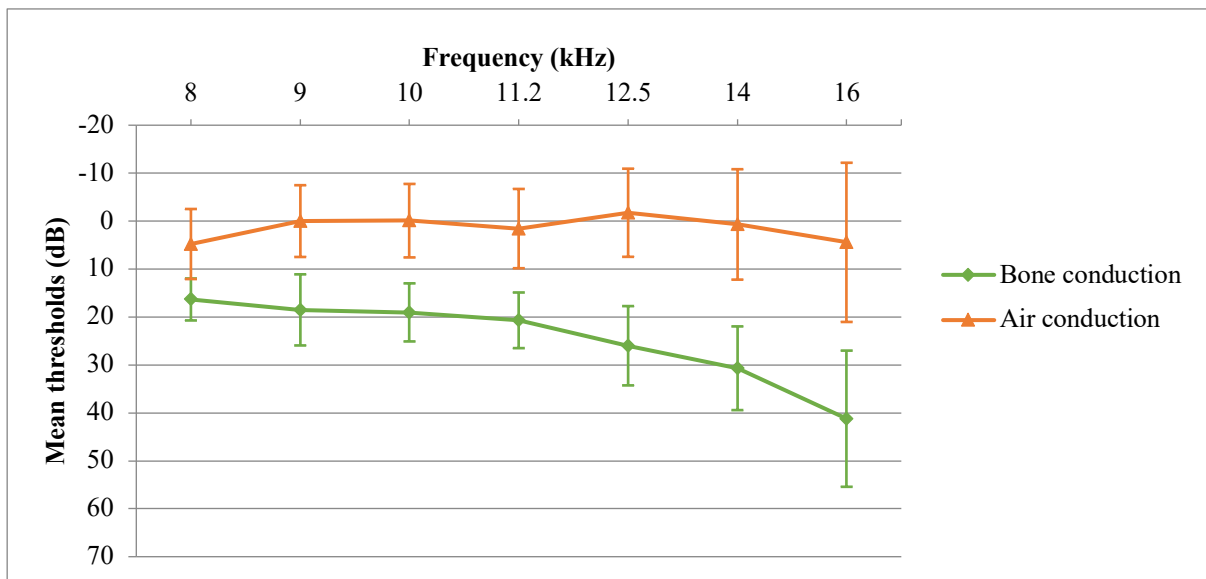


Figure 12. Mean AC thresholds measured using the GSI-61 audiometer and BC thresholds using the custom computer audiometer. AC measurements are displayed in calibrated dB HL units, whereas BC measurements are displayed in arbitrary dB units. Error bars show standard deviations.

2.2.5 *Differences between GSI-61 and custom computer audiometer thresholds*

To establish correction factors, mean differences between BC measurements collected using the custom computer audiometer and AC measurements collected via the GSI-61 audiometer were calculated for all frequencies from 8 kHz to 16 kHz. As can be seen in Figure 13, the mean values ranged from 11.6 dB to 36.3 dB, with a general increase in mean

difference with each progressing frequency up until 16 kHz. There was a large range between individuals in AC and BC threshold measurement differences, with standard deviations ranging from 6.8 dB at 10 kHz to a maximum of 10.4 at 14 kHz, as detailed in Table 1.

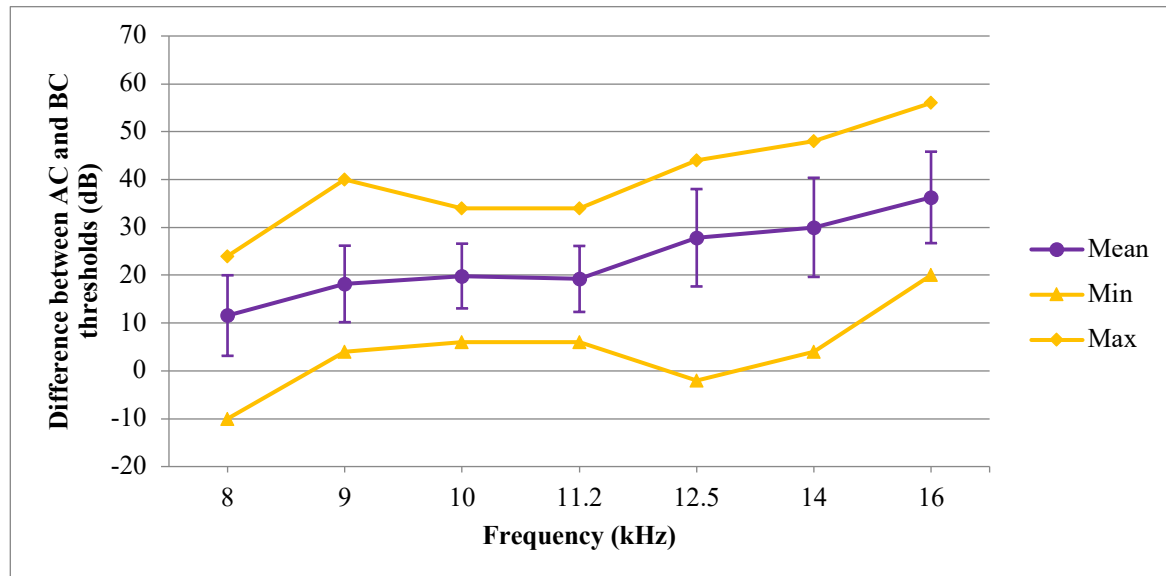


Figure 13. Mean, minimum and maximum differences between EHF AC measurements collected using the GSI-61 audiometer in dB HL and BC measurements collected using the custom computer audiometer in arbitrary dB units. Error bars show standard deviations.

Table 1. Differences between AC thresholds collected using the GSI-61 audiometer and BC thresholds collected using the custom computer audiometer in arbitrary dB units.

Frequency (kHz)	8	9	10	11.2	12.5	14	16
Mean	11.6	18.2	19.8	19.2	27.8	30.0	36.3
Standard deviation	8.4	8.0	6.8	6.9	10.2	10.4	9.6

Due to the large variability between measurements, to ensure correction factors were as accurate as possible data was also trimmed and compared to the original dataset. All values outside of the 80% CI range surrounding the mean were removed from the dataset, and the change in mean values was compared to the untrimmed raw data. This was examined to account for individual anatomical differences between participants such as skull thickness and shape, and other factors such as the stability of the transducer placement which could have resulted in the large variability between scores. Figure 14 depicts both the untrimmed and trimmed mean AC and BC threshold differences. The maximum difference between

mean thresholds of the trimmed and untrimmed data was 1.1 dB at 8 kHz, with all other calculations at any given frequency within ± 1 dB of each other, indicating that there were minimal differences in mean values between the two analyses. It was decided to utilise the trimmed data to provide a more conservative estimate of correction factors despite the minimal differences compared to the untrimmed dataset. Table 2 displays the frequency-dependent mean differences between AC and BC thresholds that were used as correction factors.

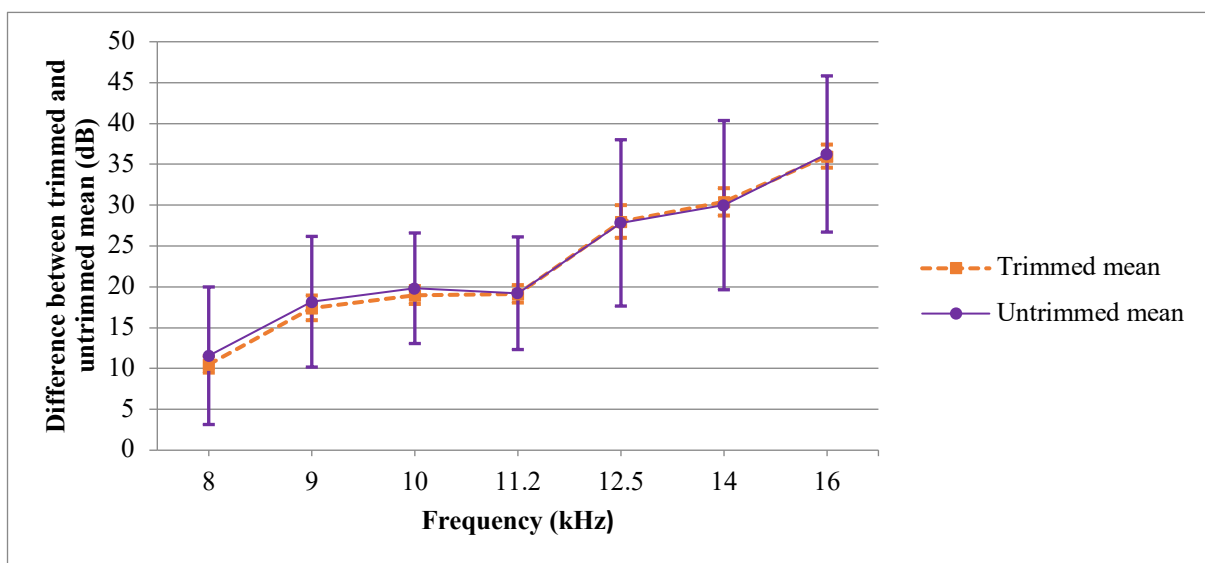


Figure 14. Difference between trimmed and untrimmed mean differences between AC and BC thresholds. Error bars show standard deviations.

Table 2. Frequency specific correction values.

Frequency (kHz)	8	9	10	11.2	12.5	14	16
Mean	10.5	17.4	19.0	19.1	28.0	30.4	36.0

2.3 Discussion

2.3.1 *Calibration of the TEAC HP-F100 BC transducer*

For calibration of the TEAC HP-F100 transducer, the real ear calibration method was chosen as described in previous research such as Babbage (2015), who measured AC thresholds from 8 – 16 kHz with a GSI-61 audiometer and again with a soundcard audiometer. BC threshold measurements were then collected using the soundcard audiometer, and compared to the AC data collected using the same audiometer. This gave an estimate of the correction values required to convert the soundcard audiometer into dB HL units. The calibration performed in the current study utilised a slightly different method, whereby mean AC thresholds in the EHF range were recorded only once using a GSI-61 audiometer, and BC thresholds in the same EHF range were measured using the TEAC HP-F100 transducer and the custom computer audiometer. In order to calibrate the transducer using this method, one key assumption was relied upon. This assumption was that EHF AC and BC threshold values in any given individual were equal to one another, on the basis that there were no significant ABGs in the CF range (0.25 – 8 kHz) for any participant. In addition, all participants displayed normal otoscopic examinations, tympanometry and acoustic reflex findings, therefore demonstrating that there were likely no conductive pathologies present in the selected sample. By operating on this assumption, it was presumed that any conductive hearing loss would be likely to affect the CF range and the EHF range equally, or in other words, isolated EHF conductive hearing loss without any indication of CF conductive hearing loss was unlikely. Several other authors have proposed this previously (Babbage, 2015; Popelka et al., 2010), and at present, there is no known evidence to contradict this assumption.

The current results also relied on the repeatability measurements of Babbage (2015), which indicated no significant changes in intra-subject test-retest reliability when the TEAC

HP-F100 transducer was used to repeat masked threshold measurements in the EHF range three times in each participant. As the same transducer and custom computer audiometer was utilised in the Babbage (2015) study to the current study, it was therefore presumed that measurements collected only once per individual were adequate to obtain reliable and clinically valid results.

2.3.2 *Establishment of correction factors*

Using a similar method to Babbage (2015), the current study provided updated correction values using the TEAC HP-F100 and custom computer audiometer, as demonstrated in Section 2.2.5. These correction values were frequency specific and were applied to BC thresholds measured using the uncalibrated TEAC HP-F100 transducer by subtracting the mean values displayed in Table 2 from the uncalibrated result.

The current method of calibration revealed large inter-subject variability in threshold measurements collected via both AC and BC transducers, and large differences between the results collected via the GSI-61 audiometer and the custom computer audiometer. This variability was likely a result of the combination of a number of factors. Firstly, the relatively small participant sample size of 23 may not have included enough participants to produce a normal distribution. Secondly, individual anatomical differences between participants such as the thickness of the skull in the forehead of each individual may have affected the transmission properties of the BC signal through the skull. In addition to this, the presence of tinnitus in some individuals during EHF testing may have also influenced AC and BC thresholds in the EHF range. This may be relevant considering Vielsmeier et al. (2015) discovered a worsening of thresholds in the EHF range in individuals with normal hearing and the presence of tinnitus, compared to a control group without tinnitus. While the presence of tinnitus is unknown in many of the participants in the study, several specifically reported how their tinnitus had interfered with their ability to distinguish the pure-tone signal from

their tinnitus, and in addition had impacted their concentration. It is possible that any of these individual factors may have contributed to large inter-subjective variations, and to account for this in the present study, data was trimmed by removing values outside of the 80% CI range to allow for a more conservative estimate of correction factors.

It is interesting to note that other studies have also found AC and BC EHF thresholds to show high variability between subjects. Hallmo et al. (1994) and Osterhammel and Osterhammel (1979) also found threshold variability typically increased with rising frequency when measuring AC in the EHF range compared to the CF range. In addition, Babbage (2015) found that standard deviations of the mean correction values typically increased with rising frequency, demonstrating a minimum of 3.6 at 9 kHz and a maximum of 8.6 at 16 kHz. In the present study, standard deviations for the mean correction values were typically larger than Babbage (2015), ranging from 6.8 at 10 kHz to 10.4 at 14 kHz. With this evidence in consideration, it appears that variability in thresholds is a commonly occurring phenomenon during clinical testing of EHF thresholds that may currently be an unavoidable issue.

2.3.3 *Conclusions*

The current method of calibration to the TEAC HP-F100 transducer using the real-ear technique has been exhibited previously as proficient for use of testing EHF thresholds (Babbage, 2015). A conservative estimate of correction values were established for the current set of results using a trimming technique to account for high inter-subject variability, and were not significantly different to the untrimmed data. Correction factors were deemed to be sufficient for use in proceeding to EHF testing in people undergoing middle ear surgery, described in the following chapter.

3.0 Measuring EHF threshold changes following middle ear procedures

As discussed in Section 1.5.2.2, few studies to date thus far have researched the ear-specific effects of middle ear surgery on AC and BC pure-tone threshold hearing acuity in the EHF range (Babbage, 2015; Doménech & Carulla, 1988; Doménech et al., 1989; Hallmo & Mair, 1996; Hegewald et al., 1989; Mair & Hallmo, 1994), and even fewer have assessed ear-specific changes to these thresholds through the use of masking (Babbge, 2015; Hallmo & Mair, 1996; Mair & Hallmo, 1994). To our knowledge, the only study to have examined both ear-specific AC and BC thresholds using masking, and how these thresholds changed over time, was the pilot study conducted by Babbage (2015), described in Section 1.5.2.2

The aim of this phase of the study was to confirm the results from the Babbage (2015) study in a larger group of participants. This was achieved by examining masked AC and BC EHF pure-tone thresholds in patients undergoing stapedectomy, ossiculoplasty and tympanoplasty procedures, to distinguish whether post-operative EHF impairment was conductive or sensorineural and how each component of the EHF hearing loss changed over the first three months after surgery. It was predicted for this phase of testing that a mixed hearing loss would be prominent immediately following surgery, with recovery over time of the conductive element so that SNHL remained. It was also anticipated that the stapes procedures would reveal higher rates of SNHL than ossiculoplasty and tympanoplasty surgeries, which were expected to display higher rates of CHL.

3.1 Method

3.1.1 Participants

This research was conducted in accordance with the Department of Otolaryngology Head and Neck Surgery, Christchurch Public Hospital, and one surgeon working within the private sector in Christchurch. Participants that were included in the study were patients undergoing middle ear. To be considered eligible, these participants were required to fulfil a set of inclusion criteria, demonstrated below:

- A. At or above the age of 16 years
- B. Scheduled to undergo either primary or revision stapedectomy/stapedotomy, tympanoplasty or ossiculoplasty.
- C. Measurable pre-operative bilateral AC thresholds up to 10 kHz or higher
- D. Average pre-operative BC thresholds at 0.5, 1 and 2 kHz no more than 50 dB HL
- E. No other significant disorders that may have resulted in an auditory or vestibular impairment
- F. Availability for pre-operative and post-operative testing

Participants considered eligible for the study based on the above inclusion criteria were invited to voluntarily join the study by the operating surgeon. All participants were given a consent form (Appendix 2) and an information sheet (Appendix 1b) outlining the study at the preadmission appointment, and written consent was obtained from all patients who agreed to join the study. Demographic information that was collected at the preadmission appointment involved patient age, sex, otologic history and symptoms, and the anticipated surgery type.

Based on the inclusion criteria listed, six participants were recruited and agreed to participate in the study. The sample included three males and three females, and the ages of the individuals ranged from 28 to 56 years old ($M = 39.3$ years, $SD = 10.2$). Two participants,

one male and one female, failed to attend any post-operative assessments and were later excluded from the study.

Table 3. Participant characteristics.

Participant	Age	Sex	Surgery type	Operative ear	Included in analysis
1	28	M	Stapedotomy	Right ear	Yes
2	43	M	Tympanoplasty	Left ear	Yes
3	47	F	Stapedotomy	Right ear	Yes
4	56	F	Ossiculoplasty	Left ear	Yes
5	32	M	Ossiculoplasty	Right ear	No
6	30	F	Stapedotomy	Right ear	No

Table 4. Summary of participant attendance to assessments.

Participant	Pre-op	1 week post-op	1 month post-op	3 month post-op
1	Yes	No	Yes	Yes
2	Yes	No	Yes	No
3	Yes	Yes	No	Yes
4	Yes	No	Yes	Yes

3.1.2 *Equipment*

Assessment was performed in sound treated rooms as required by International Organization for Standardization [ISO] 8253-1 (2010) at either at the University of Canterbury Speech and Hearing Clinics or Christchurch Public Hospital.

To assess PTA in the CF range (0.25 – 8 kHz), a calibrated GSI-61 diagnostic audiometer (Grason-Stadler, Eden Prairie, MN) was utilised. AC stimuli were presented using ER-3A insert earphones (Etymotic Research Inc., Elk Grove Village, IL). Stimuli was

also presented through TDH-39 supra-aural headphones (Telephonics Corporation, Farmingdale, NY) where insert earphones were contraindicated, for example instances of discharge, excessive wax, blood or other matter in the EAC, or if ventilation tubes or perforations (Voss et al., 2000) were present in the TM. BC stimuli (0.5 – 4 kHz) were presented via a Radioear B-71 (Radioear Corporation, New Eagle, PA) BC vibrator, which was placed on the mastoid.

As with the CF range, AC stimuli in the EHF range (8 – 16 kHz) were presented using the same GSI-61 audiometer. Sennheiser HDA 200 circumaural headphones (Sennheiser electronic GmbH & Co., Wedemark, Germany) were used to present AC stimuli in this frequency range. For BC stimuli, computer based custom audiometer software was used, written using LabVIEW 2012 (National Instruments, Austin, TX). BC stimuli were presented via TEAC HP-F100 BC headphones (TEAC, Tokyo, Japan), which had been modified in a previous study for the purpose of audiometric testing (Babbage, 2015). This device was connected to a MOTU external multi-channel sound card (MOTU, Cambridge, MA), which was connected to a laptop via USB to produce the pure-tone sound stimuli. EHF masking from 8 – 16 kHz was presented through the Sennheiser HDA 200 circumaural headphones using the GSI-61 audiometer.

3.1.3 Procedure

3.1.3.1 General procedure

For each participant, a pre-operative assessment was conducted at one month or less before the scheduled surgery. This consisted of an otoscopic examination, and bilateral AC and BC audiometry in both the CFs and the EHF. This assessment procedure was repeated at approximately one to two weeks, one month and three months following the surgical procedure, with exact intervals dependent on the timing of follow-up appointments with the otologist.

3.1.3.2 *Conventional frequency pure-tone audiometry*

Hearing thresholds for continuous pure-tone stimuli were measured in 5 dB HL step increments using the Modified Hughson-Westlake technique (Carhart & Jerger, 1959). For AC, threshold measurements were obtained at octave frequencies from 0.25 kHz - 8 kHz, and at 3 kHz in both ears. When interaural attenuation values, as outlined by Katz, Chasin, English, Hood, and Tillery (2015), between the AC thresholds of the test ear and the AC or BC thresholds of the non-test ear were exceeded for any given frequency or transducer, narrow-band masking noise was presented to the contralateral ear using the selected transducer.

For BC testing, the vibrator was positioned on the mastoid, and measurements were obtained at octave frequencies from 0.5 kHz - 4 kHz, and in addition at 3 kHz. Contralateral narrow-band masking was utilised where there was a difference between the AC and BC threshold at a particular frequency in the test ear of 15 dB HL or more. Narrowband masking noise was also presented in the non-test ear during all BC testing in the CF range. All masking used a step masking technique described by Yacullo (1996).

3.1.3.3 *Extended high frequency pure-tone audiometry*

Using the circumaural headphones, AC stimuli was presented at 1/6th octave frequencies from 8 - 16 kHz in both ears. 5 dB HL step increments were used to obtain hearing thresholds in response to continuous pure-tone stimuli, using the Modified Hughson-Westlake technique (Carhart & Jerger, 1959). “No response” was recorded on the audiogram when the participant did not press the button after two repetitions at the limit of the audiometer for any given frequency. A step masking technique was applied to present narrowband masking noise via the Sennheiser HDA 200 headphones if the AC thresholds in the test ear and the AC or BC thresholds in the non-test ear differed by the conservative interaural attenuation value of 40 dB HL, based on research conducted by Brännström and

Lantz (2010). Due to the reduced dynamic range of the audiometer in the EHF range, where adequate masking could not be obtained as a result of reaching the output limits of the audiometer, an asterisk was marked on the audiogram to indicate this.

For BC stimuli, the TEAC bone vibrator was positioned on the forehead as close to the midline as possible. BC stimuli was presented at 1/6th octave frequencies from 8 - 16 kHz in both ears. Contralateral EHF narrowband masking was always applied to the non-test ear at 30 dB HL above the AC thresholds for that same ear at the test frequency. Where adequate masking levels could not be reached an asterisk was written next to the test frequency it applied to on the audiogram.

3.1.4 *Data analysis*

Due to the low number of participants recruited, data was analysed using a case study approach. For each of the assessment brackets, discussed below in Section 3.1.4.1, changes in AC thresholds from 0.25 – 16 kHz and BC thresholds from 0.5 – 16 kHz in both the operated and non-operated ears were calculated by subtracting the post-operative from the pre-operative threshold. Positive numbers indicated threshold improvement, whereas negative numbers indicated a worsening of hearing thresholds. In instances where hearing thresholds could not be measured before the limits of the audiometer were reached, the threshold was determined as 5 dB HL above the output level for that particular frequency for calculation purposes. The number of measurable test frequencies lost was also calculated, for example, if a threshold was measurable at 16 kHz before surgery but the highest threshold was 14 kHz post-operatively, this was defined as one test frequency lost.

In addition to these measures, changes to ABGs were also examined in the operated ear and the non-operated ear. The difference between the AC and the BC thresholds at each BC test frequency for each post-operative assessment was calculated and compared to pre-operative data. A value of 0 dB HL indicated equal AC and BC thresholds. Positive

deviations from 0 dB HL indicated ABGs, whereby the further the deviation from 0 dB HL, the larger the ABG presence. ABGs of 15 dB HL or more were defined as significant.

3.1.4.1 Assessment brackets

As timing of assessments varied across participants, assessments were grouped according to the number of days after surgery testing was performed and labelled as follows:

Pre-operative = 1 – 30 days pre-surgery

One week = 1 – 20 days post-surgery

One month = 21 – 59 days post-surgery

Three months = 60 – 134 days post-surgery

3.2 Results

3.2.1 Case A

Participant A was a 28 year old male with a rapidly progressive CHL and a clinical diagnosis of otosclerosis. A right stapedotomy was undertaken using a speculum to elevate the posterior tympanomeatal flap, with stapes fixation and a thin footplate with anterior focus of otosclerosis confirmed intra-operatively, before removal of the stapes superstructure via a laser. A 0.8mm stapedotomy was performed using a CO₂ laser, a gauge needle and hand drill, with a 4.75 x 0.6mm 360° prosthesis placed into the vestibule and secured to the long process of the incus using the laser. At the end of the procedure, a small tear on the inferior part of the tympanomeatal flap was repaired using an underlay graft method.

Pre-operative audiometric data, displayed in Figure 15 showed a bilateral CHL, most notable in the operated ear (right ear) with a moderately-severe hearing loss rising to a mild hearing loss in the CF range and measurable thresholds in the EHF range up to 16 kHz. The left ear also displayed a mild hearing loss CF range, rising to normal levels from 2 kHz up to 14 kHz, sloping to a mild hearing loss at 14 and 16 kHz.

3.2.1.1 *Changes in AC pure-tone thresholds*

As shown in Figure 16, at the one month post-operative assessment there was an improvement in the CF range AC thresholds of the operated ear when compared to pre-operative thresholds, with maximum improvement of thresholds at 1 and 2 kHz (40 dB HL). Improvements were prominent at some lower frequencies within the EHF range (8 – 9 kHz), however an increase in AC thresholds was evident from 10 – 16 kHz, up to a maximum at 12.5 kHz (10 dB HL). AC thresholds in the operated ear improved further at the three month assessment, with frequencies up to 12.5 kHz improving or remaining stable relative to one month data. Despite considerable gains in the CF range, 14 - 16 kHz AC thresholds remained the same as pre-operative levels, demonstrating a moderate hearing loss in the EHF.

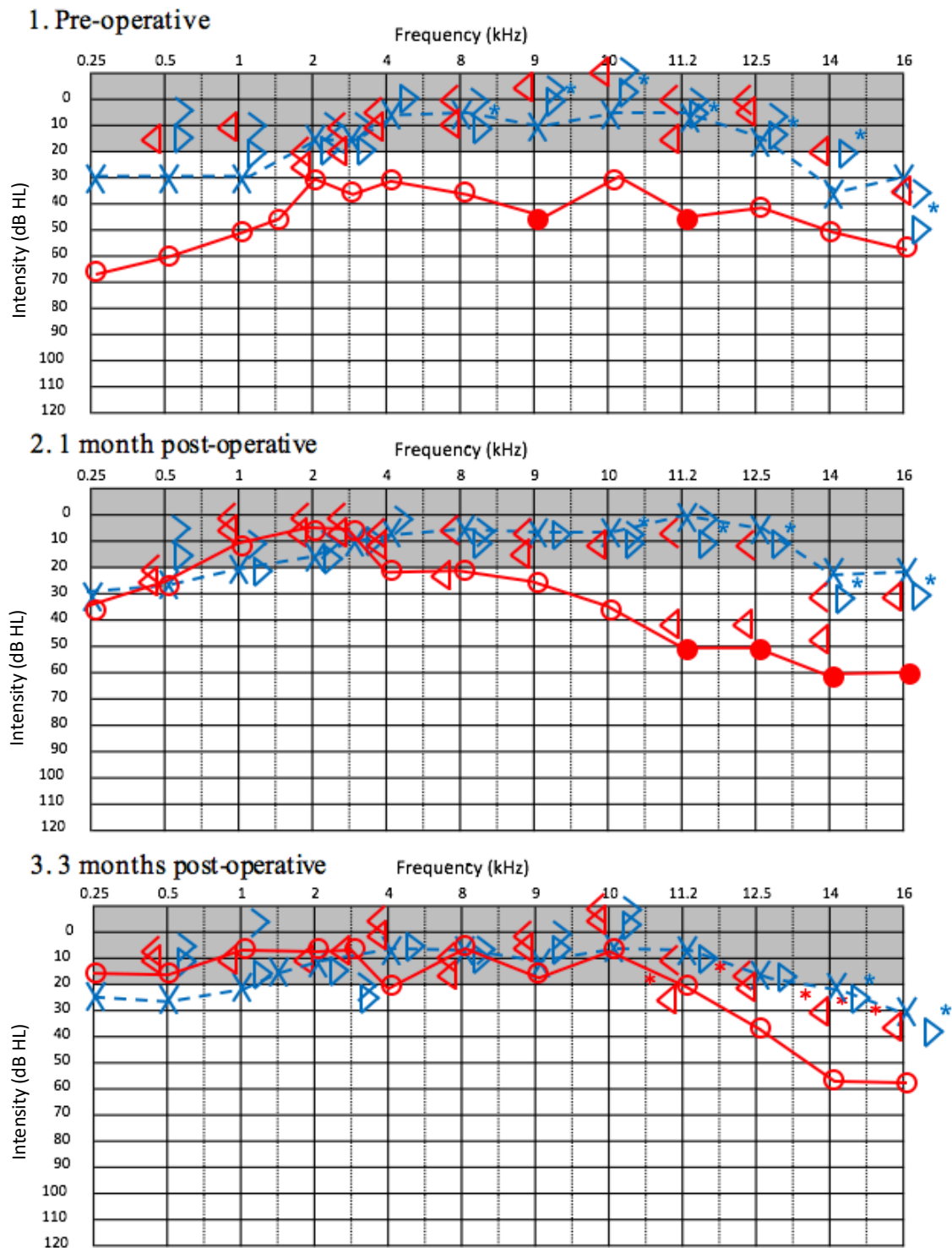


Figure 15. Audiograms for participant A pre-operatively (1), one month following surgery (2) and three months following surgery (3). Instances of potentially insufficient masking levels are indicated by asterisks.

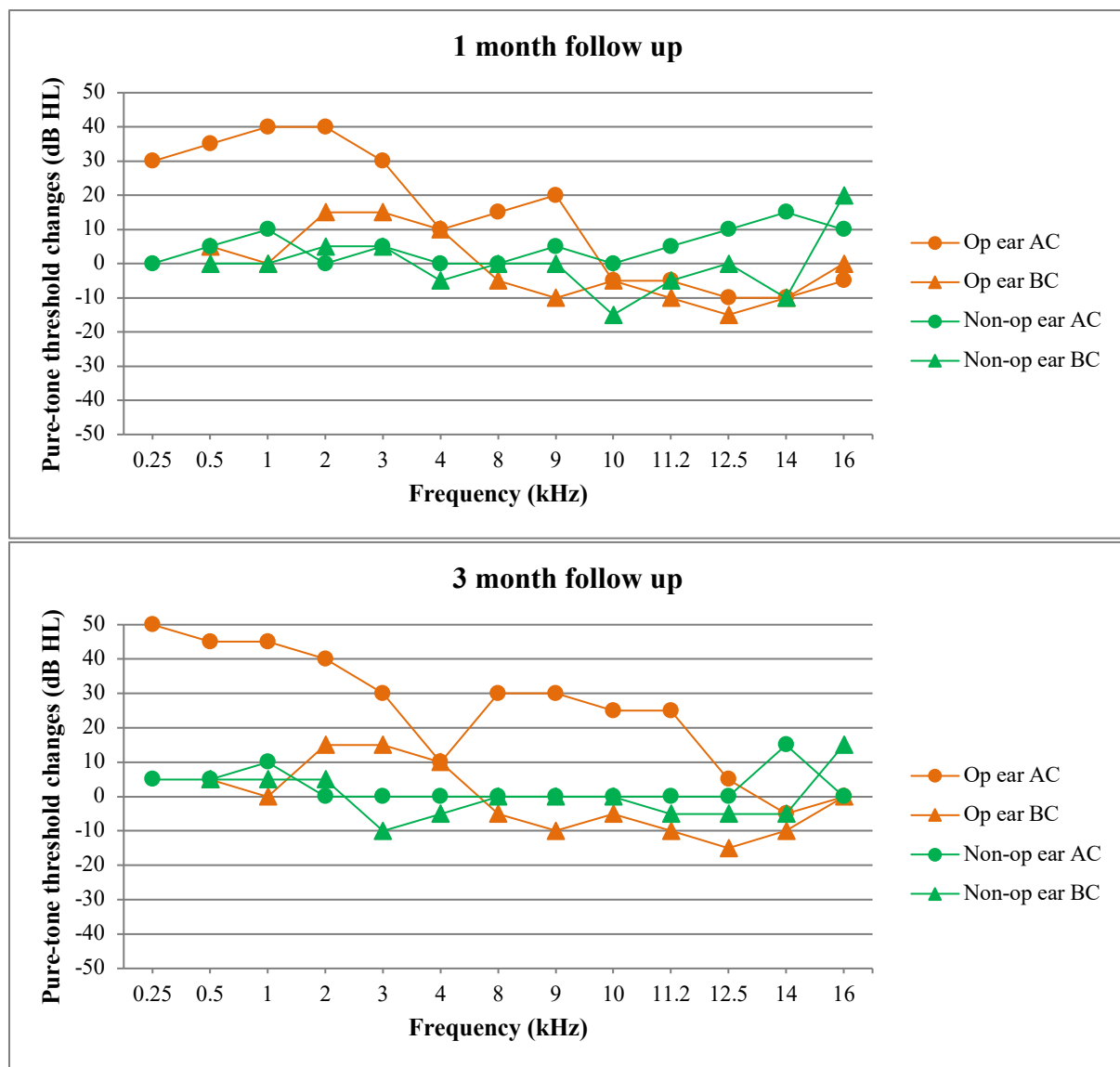


Figure 16. Changes in air conduction and bone conduction thresholds for participant A in both the operated ear and the non-operated ear from the pre-operative assessment, at both the one month (top chart) and three month (bottom chart) follow up. Improvements in thresholds are indicated by positive numbers, whereas negative numbers indicate an increase in thresholds.

3.2.1.2 Changes in BC pure-tone thresholds

As demonstrated in Figure 16, BC thresholds in the CF range (0.5 kHz – 4 kHz) for the operated ear improved at all frequencies at the one month follow up assessment when compared to the pre-operative data, with the exception of 0.5 kHz. Recovery of 0.5 kHz was prominent at the three month follow up assessment, with an improvement of 10 dB HL at the three month follow up from 25dB HL at the one month follow up.

In the EHF range of the operated ear, there was an increase in BC thresholds at all frequencies from 8 kHz - 16 kHz at the one month follow up, indicating a mild to moderate SNHL hearing loss at the frequencies of 9 - 16 kHz. There was partial recovery at the three month follow up of EHF thresholds, however all frequencies were at least 5 dB worse than BC thresholds obtained at the pre-operative levels, to a maximum of 15 dB HL at 12.5 kHz.

3.2.1.3 Changes to the air-bone gap

Figure 17 depicts changes to the size of the ABG over the post-operative period. In the CF range, at both one month and three months post-operatively it can be seen that at all frequencies the ABG significantly decreased from pre-operative levels, resulting in a closure of the ABG with the exception of 4 kHz.

The EHF range also exhibited a decrease to the size of the ABG across all frequencies at both the one and three month follow ups. However, unlike with the CF range whereby AC thresholds improved to close the ABG, the size of the ABG at the one month assessment was likely reduced due to BC thresholds at all frequencies except 16 kHz increasing closer to the level of the AC thresholds, indicating SNHL. There was however, a significant ABG (≥ 15 dB) at the frequencies of 10, 14 and 16 kHz, indicating mixed hearing loss at these frequencies. At three months, the closure of the ABG from 8 – 11.2 kHz was due to improved AC thresholds, with a significant ABG apparent at 14 and 16 kHz, again reflective of mixed hearing loss. A possible explanation for the conductive component of the EHF loss is that, due to the limits of the audiometer, insufficient masking was able to be provided to establish the true BC threshold, which may be closer to that of the AC threshold. There were no significant changes to the non-operative ear across the assessments.

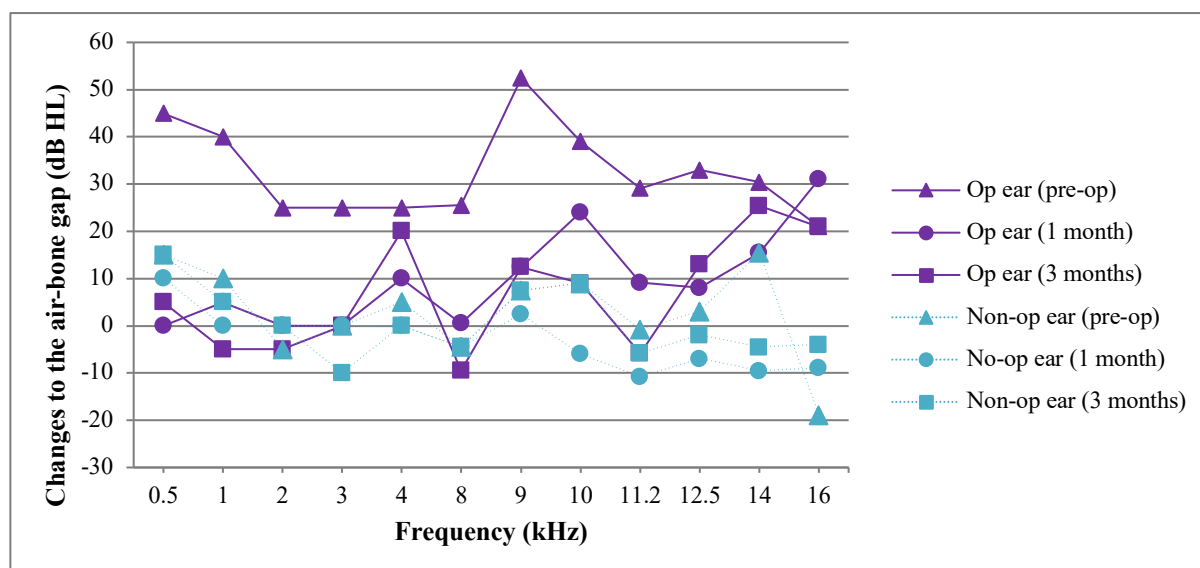


Figure 17. Differences between air conduction and bone conduction results for participant A in the operative ear and the non-operative ear at the pre-operative, one month post-operative and three months post-operative assessments. Larger numbers indicate a larger air-bone gap, with proximity to 0 indicating equal air conduction and bone conduction thresholds.

3.2.2 Case B

This 43 year old male had a history of bilateral middle ear infections and was scheduled to undergo middle ear surgery in his left ear, with the type of surgery to be determined based on intra-operative findings. The patient had a clinical diagnosis of CSOM with cholesteatoma secondary to a perforation of the TM. As shown in Figure 18, pre-operatively, a moderately-severe rising to mild and sloping back to moderately-severe mixed hearing loss in the CF range was evident in the left ear, and a further decline in the EHF range from 8 kHz - 12.5 kHz was present. Thresholds at all frequencies above 12.5 kHz in the left ear were unable to be measured before reaching the output limits of the audiometer.

A tympanoplasty was performed, whereby an incision was made into the EAM, with a vascular strip elevated and separated from the TM posteriorly. A canalplasty was undertaken using cutting and diamond burrs, and a new annulus was drilled with a 1mm diamond burr. All disease was removed and a temporalis fascia graft was placed under the handle of the malleus. There were no reported intra-operative or post-operative complications.

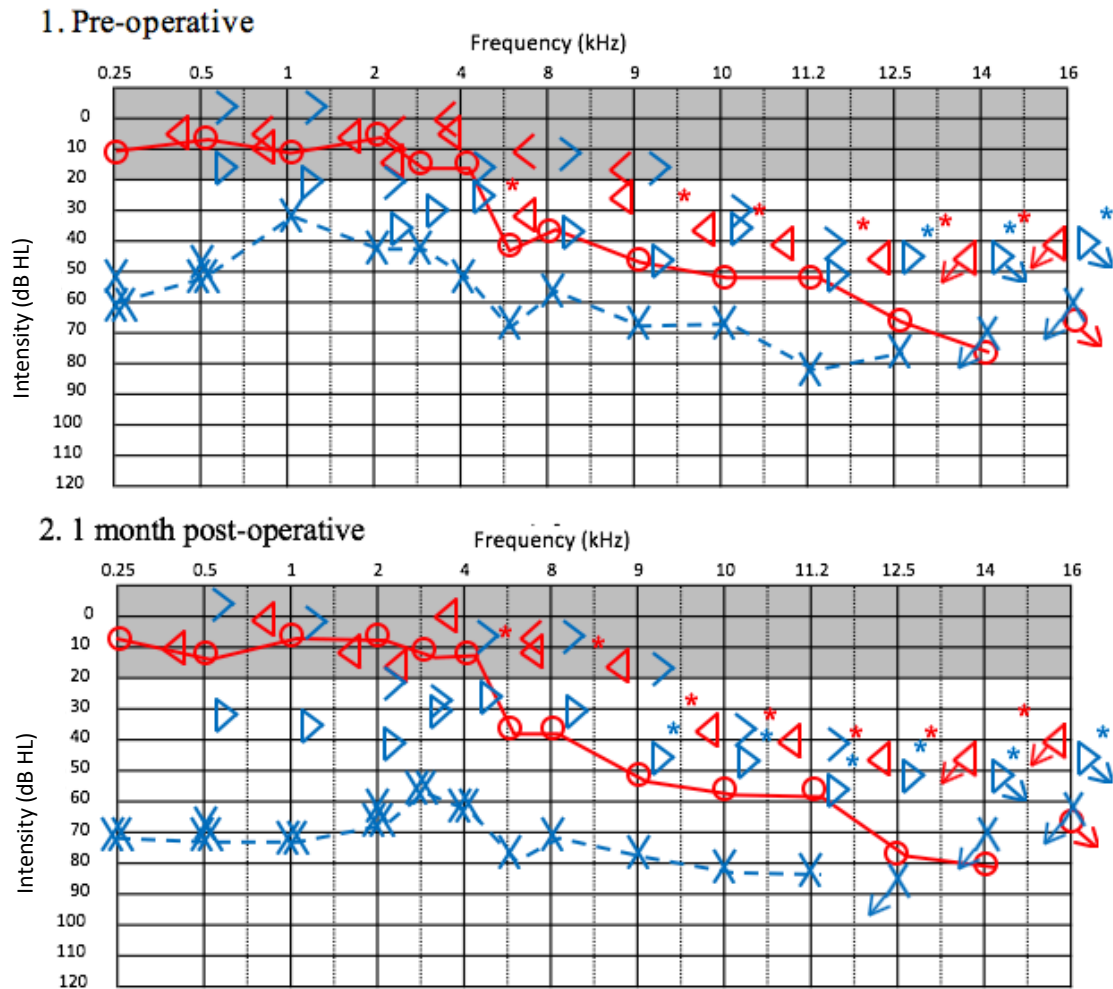


Figure 18. Audiograms for participant B pre-operatively (1) and one month following surgery (2). Instances of potentially insufficient masking levels are indicated by asterisks.

3.2.2.1 Changes in AC pure-tone thresholds

As illustrated in Figure 18 and 19, in the CF range there was a significant decline in the operative ear AC hearing thresholds at the one month post-operative assessment, which was not present in the contralateral ear. The greatest elevation in thresholds occurred at 1 kHz, which increased by 40 dB HL. Likewise, there was also an increase in AC thresholds in the EHF range, with a significant increase of 15 dB HL at 8, 10 kHz and 12.5 kHz, and 10 dB HL at 9 kHz. There was a loss in the highest measurable frequency before output limits of the audiometer were reached of one, decreasing from 12.5 kHz pre-operatively, to 11.2 kHz in the operated ear. In the contralateral ear, there was no change to measurable frequencies.

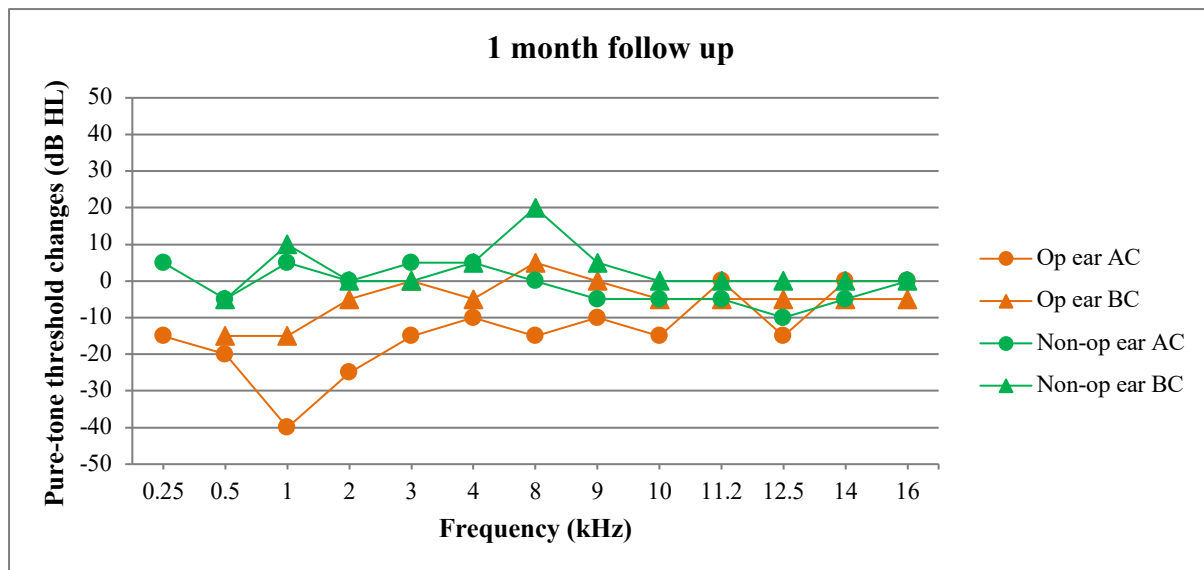


Figure 19. Changes in air conduction and bone conduction thresholds for participant B in both the operated ear and the non-operated ear from the pre-operative assessment at the one month follow up. Improvements in thresholds are indicated by positive numbers, whereas negative numbers indicate an increase in thresholds.

3.2.2.2 Changes in BC pure-tone thresholds

Figure 19 above shows the elevation of BC thresholds in both the CF range and EHF range of the operative ear at the one month post-operative stage relative to the pre-operative data. With the exception of 3, 8 and 9 kHz, all other frequencies had an increase in BC hearing thresholds of at least 5 dB HL, to a maximum of 15 dB HL at 0.5 and 1 kHz. The non-operative ear did not demonstrate significant changes to EHF BC thresholds.

3.2.2.3 Changes to the air-bone gap

As shown in Figure 20, the size of the ABG in the operative ear from the pre-operative to the one month post-operative assessment increased at almost all frequencies from 0.5 – 16 kHz, with the exception of 11.2, 14 and 16 kHz. The maximum ABG was 40.5 dB HL at 8 kHz at the one month follow up. Due to the significant increase in both AC thresholds and BC thresholds in the operative ear, with a larger increase in AC thresholds, it appears as though a combination of SNHL and CHL has occurred. Unfortunately, no three month follow up data was available to assess further changes over time.

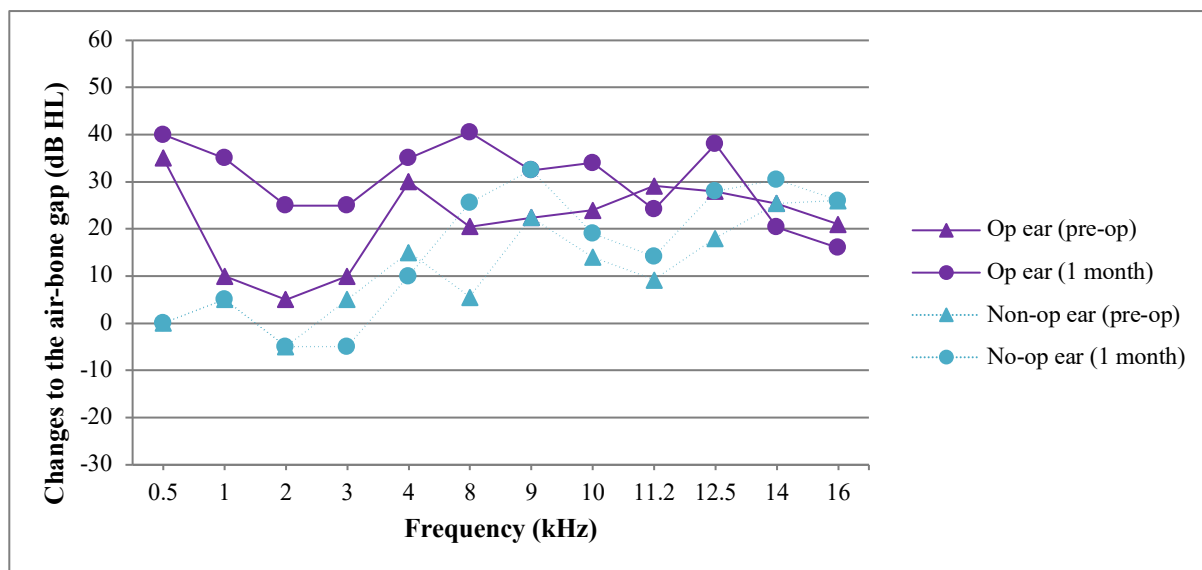


Figure 20. Differences between air conduction and bone conduction results for participant B in the operative ear and the non-operative ear at the pre-operative and one month post-operative assessments. Larger numbers indicate a larger air-bone gap, with proximity to 0 indicating equal air conduction and bone conduction thresholds.

3.2.3 Case C

Participant C was a 46 year old woman with a clinical diagnosis of otosclerosis in the right ear, with a moderate rising to mild and sloping to moderately-severe primarily conductive hearing loss in the in the CF range, and measurable thresholds up to 10 kHz (Figure 21). Participant C underwent a successful stapedotomy procedure in her right ear three years prior.

Intra-operatively, a fixed stapes with thin footplate was discovered with a mobile incus and malleus. Using a speculum, a tympanomeatal flap was elevated and the scutum was curetted for access into the middle ear cavity. Vessels around the oval window were coagulated with a CO₂ laser, and the incudostapedial joint was divided. The laser was then used to divide the stapedius tendon and both crura, and the stapes superstructure was removed. A 0.8mm stapedotomy was made with the laser, a straight needle and a hand drill, and a 4.5 x 0.6mm 360° SMart prosthesis was placed into the vestibule and attached to the long process of the incus using the laser. There were no reported instances of intra-operative or post-operative complications.

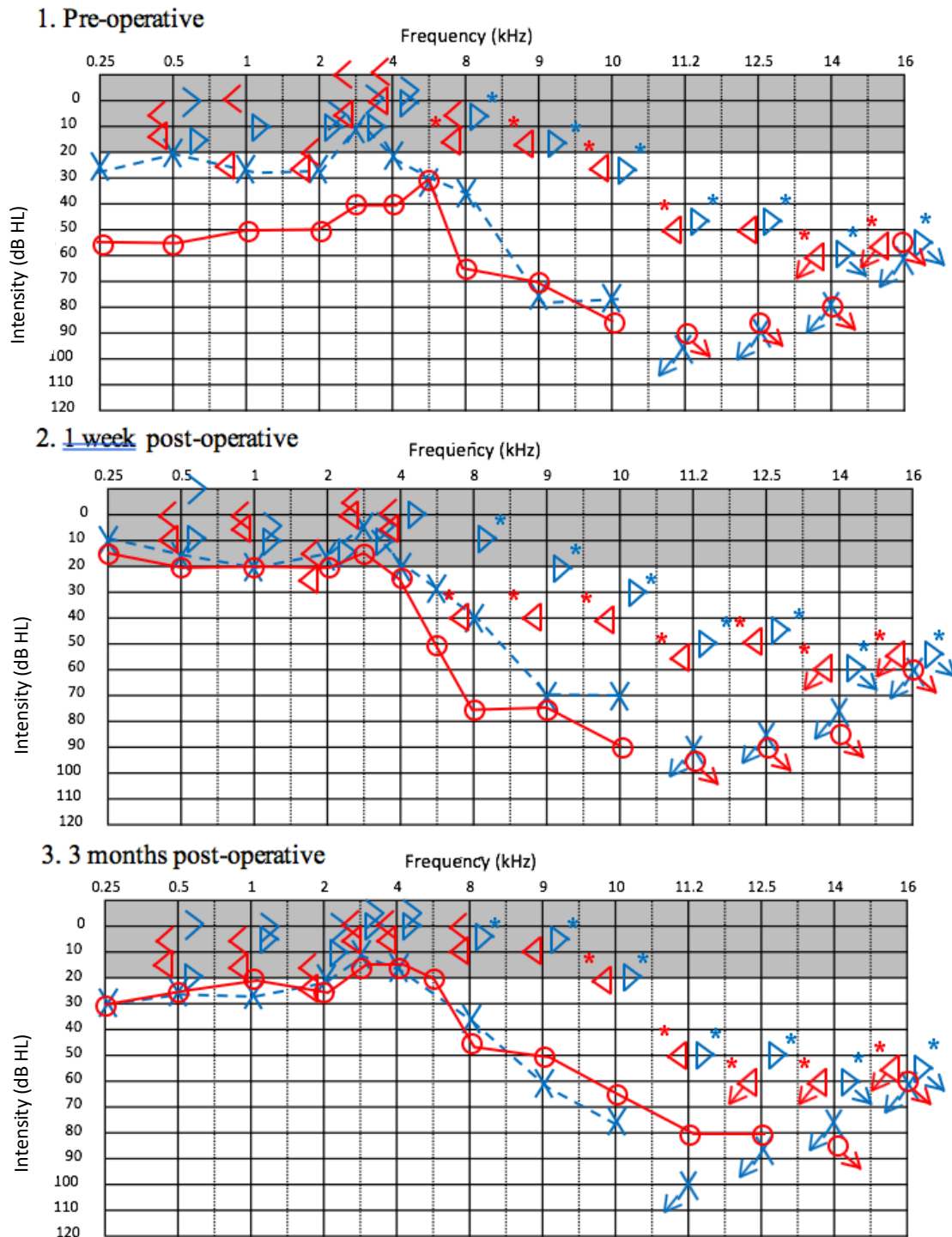


Figure 21. Audiograms for participant C preoperatively (1), one week following surgery (2) and three months following surgery (3). Instances of potentially insufficient masking levels are indicated by asterisks.

3.2.3.1 Changes in AC pure-tone thresholds

From Figure 22, it can be seen that at the one week post-operative assessment there was a significant improvement to the operative ear AC thresholds in the CF range from 0.25 – 4

kHz when compared to pre-operative data. Maximum improvement of 40 dB HL was obtained at 0.25 kHz, and improvements typically lessened with increasing frequency up to 4 kHz. In the EHF range, there was a threshold increase of at least 5 dB HL across all frequencies from 8 – 16 kHz. At the three month post-operative assessment, thresholds at 0.5 – 3 kHz remained stable, within +/- 5 dB HL of the one week follow up data. While there was an increase at 0.25 kHz of 15 dB HL, there was a significant improvement to all frequencies at and above 4 kHz, with the exception of 14 and 16 kHz, at which thresholds could not be recorded before reaching the output limits of the audiometer.

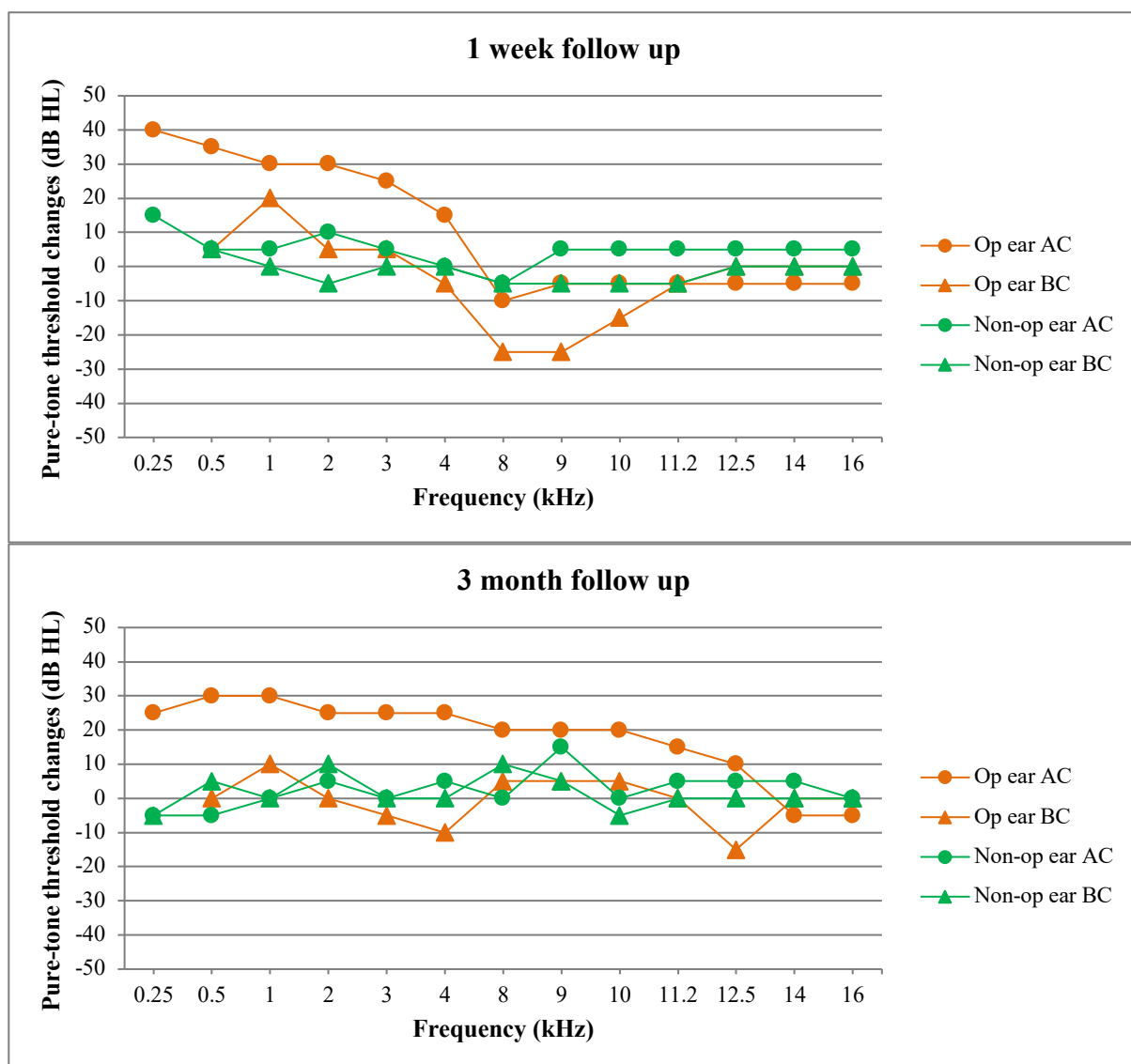


Figure 22. Changes in air conduction and bone conduction thresholds for participant C in both the operated ear and the non-operated ear from the pre-operative assessment, at both the one week (top chart) and three month (bottom chart) follow up. Improvements in thresholds are indicated by positive numbers, whereas negative numbers indicate increases to thresholds.

3.2.3.2 *Changes in BC pure-tone thresholds*

One week post-operatively, BC thresholds in the operative ear improved in the CF range, and then worsened with increasing frequency. At 8 and 9 kHz, there was an increase of 25 dB HL from the pre-operative assessment, indicating potential sensorineural injury. Likewise with the pre-operative assessment, thresholds exceeded the limits of the audiometer at 14 and 16 kHz. There was a loss of one test frequency at three months from 14 kHz pre-operatively and at the one week follow up to 12.5 kHz at the three month assessment.

At the three month follow up, thresholds in the CF range remained stable, with no changes to BC thresholds more than +/- 10 dB HL. In general, the EHF range up to 11.2 kHz recovered from the one week follow up significantly, aside from 12, 14 and 16 kHz, which were unmeasurable. Despite significant AC improvements at 12.5 kHz at three months post-operatively, there was a decline of BC thresholds from 50 dB HL at the one week assessment to being unmeasurable at 60 dB HL at three month post-operatively, indicating a SNHL of at least 15 dB HL.

3.2.3.3 *Changes to the air-bone gap*

From Figure 23, it is clear that there were significant improvements to the ABG in the operative ear from the pre-operative assessment to both post-operative assessments. The ABG was improved most prominently in the CF range up to 8 kHz, with all test frequencies showing improvements by the one week follow up, and improving further at the three month follow up. The ABG had reduced to within 10 dB HL from 0.5 – 4 kHz by the three month follow up, but remained significant from 8 kHz onwards, ranging from 13 – 39 dB HL. At both the one week and three month follow ups, there was a large ABG in the EHF range at all of the measurable frequencies up to 12.5 kHz. At 12 kHz, the ABG was relatively consistent from the pre-operative assessment to the one week follow up, but reduced to 20 dB HL at the three month follow up. This was due to a combination of long-term AC improvement despite

a deterioration to BC thresholds compared to pre-operative and one week follow up data. At 14 and 16 kHz, for all assessments it was unable to be determined whether an ABG was present, as both AC and BC thresholds were unmeasurable. There were no significant changes to the non-operative ear, which continued to show a significant ABG in the EHF's at all assessments.

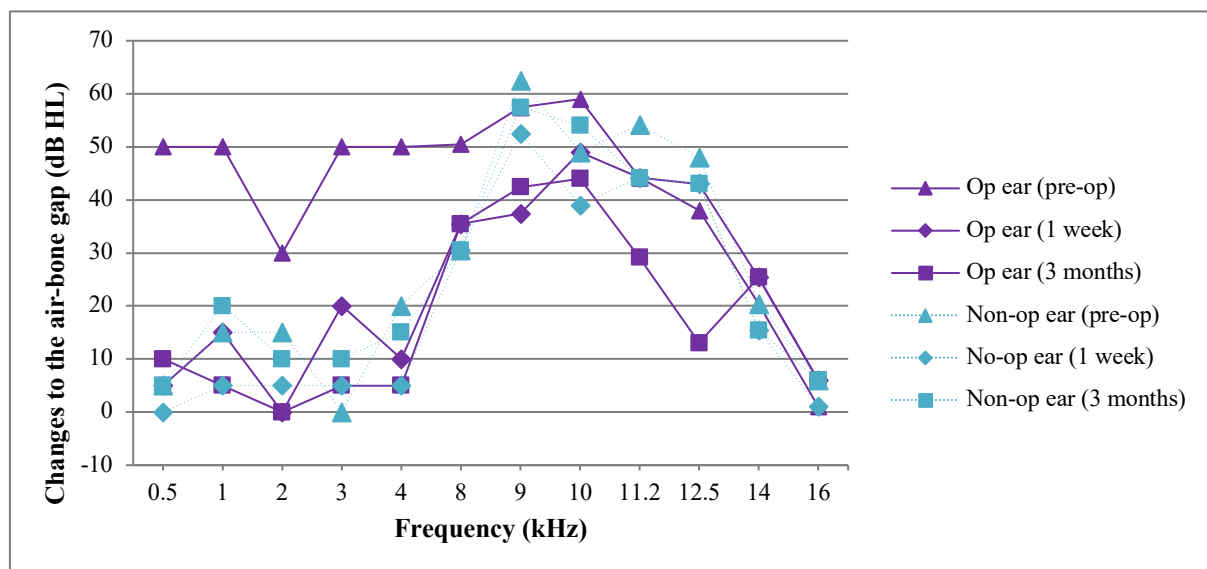


Figure 23. Differences between air conduction and bone conduction results for participant C in the operative ear and the non-operative ear at the pre-operative, one week post-operative and three months post-operative assessments. Larger numbers indicate a larger air-bone gap, with proximity to 0 indicating equal air conduction and bone conduction thresholds.

3.2.4 Case D

Participant D was a 56 year old woman who had a hearing loss in the left ear resulting from a traumatic fracture to the temporal bone. Pre-operatively, AC thresholds in the left ear demonstrated a mild to moderately-severe mixed hearing loss, with thresholds that were measurable up to 14 kHz. All BC thresholds were measurable up to 16 kHz (Figure 24). Middle ear surgery was scheduled with the procedure to be decided dependent on intra-operative findings. The surgery consisted of a cortical mastoidectomy and ossiculoplasty, and was combined with a craniotomy procedure to repair the encephalocele. Intra-operatively, an extended post auricular incision was made and a large sub-periosteal flap was raised. A cortical mastoidectomy was performed using a cutting burr. A posterior tympanotomy was

performed using cutting and diamond burrs, and a fixed incus and malleus with a mobile stapes was identified. The incus buttress was burred down, and the incudostapedial joint was disarticulated, with removal of the incus and malleus. An ossiculoplasty was performed using a size 2.5 Kurtz PORP prosthesis. Partway through the procedure, a neurosurgical team joined and performed a craniotomy via a trans-mastoid and middle fossa approach for repair of encephalocele. There were no reported intra-operative or post-operative complications.

3.2.4.1 Changes to AC pure-tone thresholds

As shown in Figure 24 and 25, there was a significant improvement at the one month follow up assessment for all AC thresholds at frequencies up to 6 kHz in the operative ear. This improvement remained at the three month follow up assessment, although a small threshold increase was recorded at 0.25 - 0.5 kHz.

Despite improvements to AC thresholds in the CF range, deterioration in hearing was recorded in the EHF range at both the one and three month follow ups for the operative ear. At the one month follow up, all frequencies had an increase in AC thresholds of 5 dB HL or more, with a maximum increase of 30 dB HL at 12.5 kHz. The exception to this was 16 kHz, which was unmeasurable at all assessments. The increase in AC thresholds continued at the three month follow up, with a 30 dB HL drop from pre-operative thresholds at 10 and 11.2 kHz. There was a loss in the operative ear of the highest measurable AC frequency of two, decreasing from 14 kHz at the pre-operative assessment to 11.2 kHz at the one month follow up. There was partial recovery of AC thresholds at the three month follow up, with the highest measurable threshold increasing to 12.5 kHz.

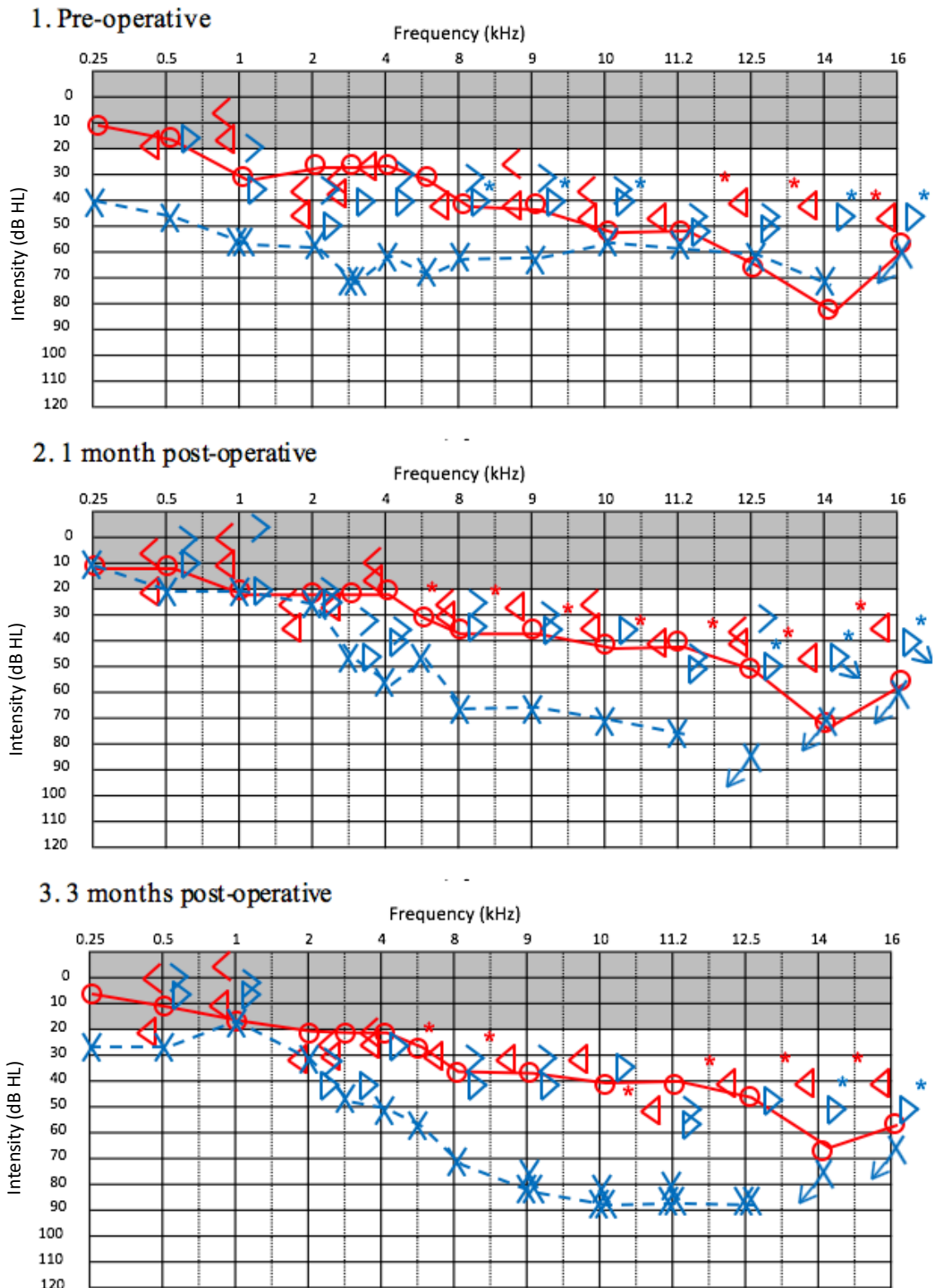


Figure 24. Audiograms for participant D at the pre-operative stage (1), one month following surgery (2) and three months following surgery (3). Instances of potentially insufficient masking levels are indicated by asterisks at the frequency affected.

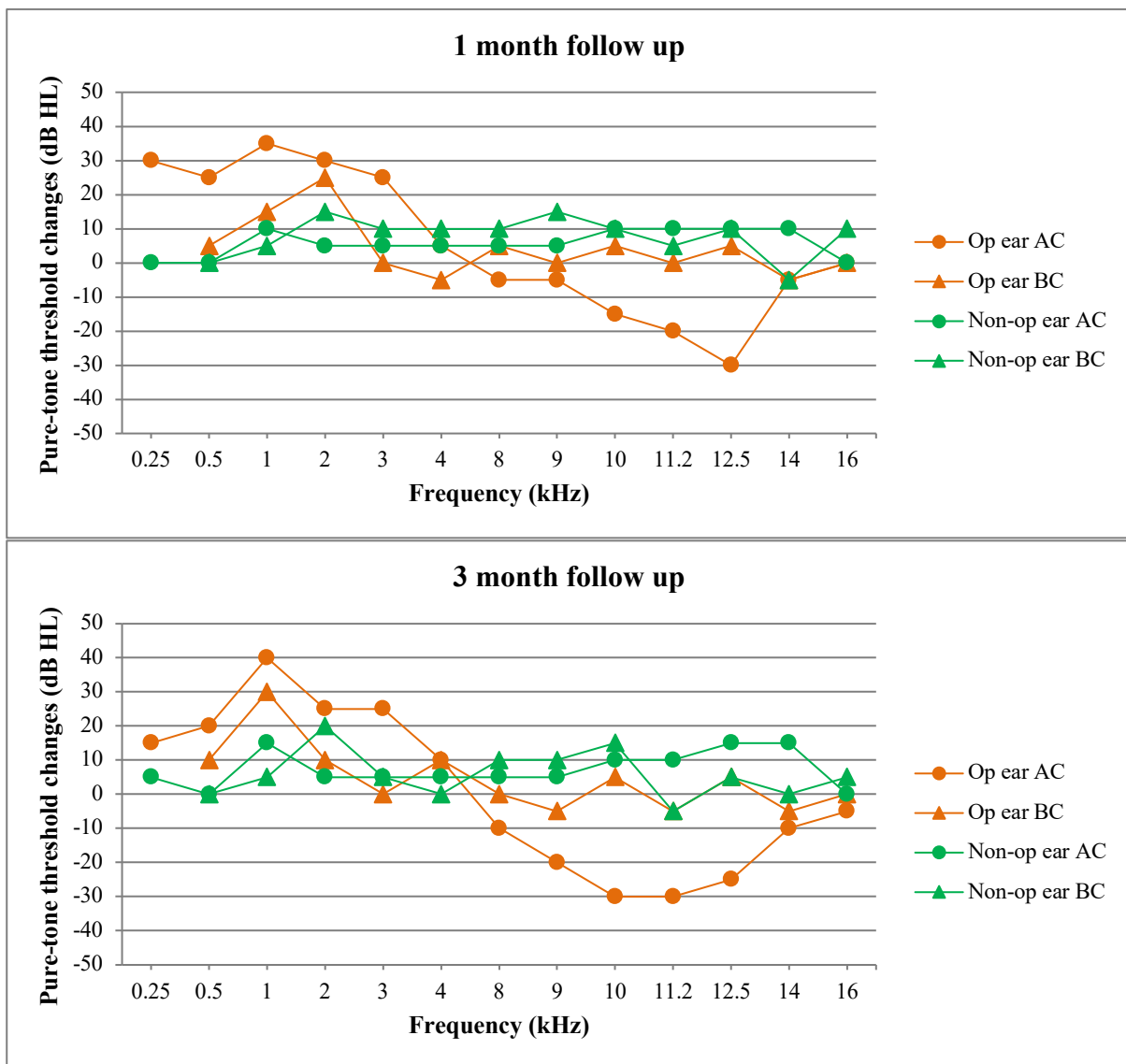


Figure 25. Changes in air conduction and bone conduction thresholds for participant D in both the operated ear and the non-operated ear from the pre-operative assessment, at both the one week (top chart) and three month (bottom chart) follow up. Improvements in thresholds are indicated by positive numbers, whereas negative numbers indicate increases to thresholds.

3.2.4.2 Changes to BC pure-tone thresholds

At the one month follow up, as shown in Figure 25, BC thresholds at 0.5 – 3 kHz improved from the pre-operative thresholds, in particular at 2 kHz, with a 25 dB HL improvement in the operative ear. From 4 kHz onwards, BC thresholds remained within +/- 5 dB HL of the pre-operative threshold at all frequencies. Likewise, at the three month follow up from 8 kHz onwards all thresholds were within 5 dB HL of the pre-operative thresholds. Of particular interest was 14 and 16 kHz BC thresholds, which were unmeasurable at the one month post-operative assessment at 45 dB HL and 40 dB HL, respectively. This corresponds

to a loss to the highest measurable frequency of two at the one month assessment period, with recovery of BC thresholds to within ± 5 dB HL of pre-operative levels at 14 - 16 kHz at the three month assessment.

3.2.4.3 *Changes to the air-bone gap*

As shown in Figure 26, in general the ABG size decreased in the CF range following surgery at the one and three month follow up due to improvements to AC thresholds, whereas the size of the ABG in the EHF region increased following the surgery. From the one month follow up to the three month assessment, there was an increase in the ABG size from 9 – 11.2 kHz ranging from 5 – 15 dB HL. This was likely a result of increases to AC thresholds, with all BC thresholds in the EHF range remaining within ± 5 dB HL of the one month follow up data. ABGs in the non-operative ear did not change significantly post-operatively.

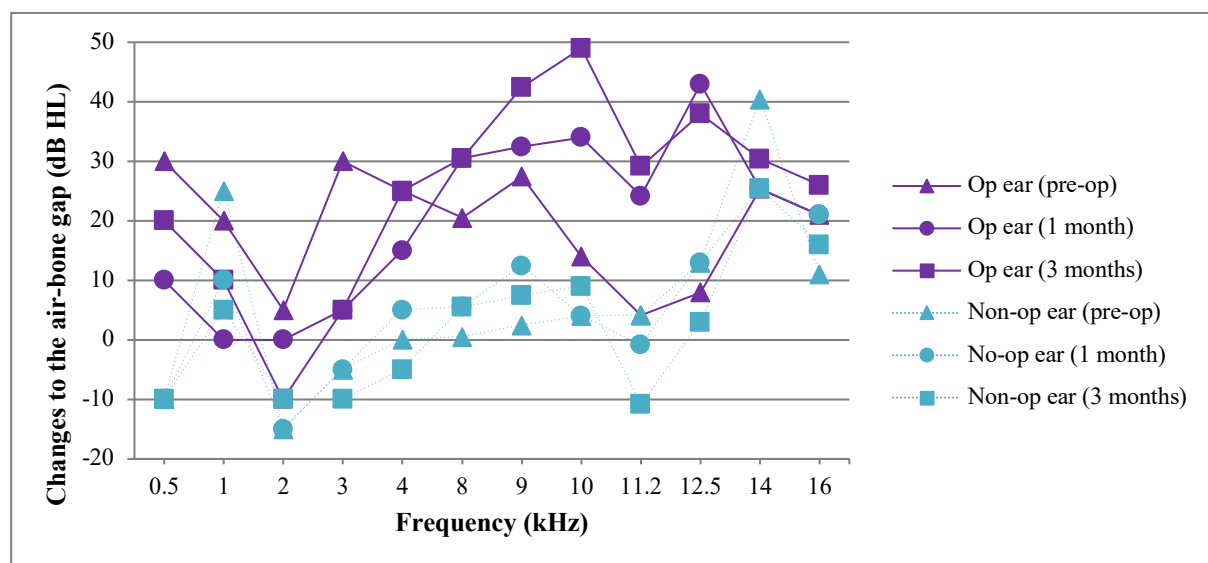


Figure 26. Differences between air conduction and bone conduction results for participant D in the operative ear and the non-operative ear at the pre-operative, one week post-operative and three months post-operative assessments. Larger numbers indicate a larger air-bone gap, with proximity to 0 indicating equal air conduction and bone conduction thresholds.

3.3 Discussion

It has been well established in previous literature that EHF hearing impairment is a common occurrence following middle ear surgery (Babbage, 2015; Doménech & Carulla, 1988; Doménech et al., 1989; Hallmo & Mair, 1996; Hegewald et al., 1989; Laukli & Mair, 1985; Mair & Hallmo, 1994; Mair & Laukli, 1986; Tange & Dreschler, 1990). Despite this, there remains a lack of data regarding post-operative ear-specific changes to EHF BC thresholds. The pilot study (Babbage, 2015) described in Section 1.5.2.2 provided preliminary evidence to support the hypothesis that both conductive and sensorineural hearing loss within the EHF range occurs in at least some cases following otosclerosis and ossiculoplasty surgeries.

The aim of the current study was to confirm the results of the Babbage (2015) study in a larger group of participants, to distinguish the characteristics of EHF hearing impairment following middle ear surgery, and how this changes over the first three months after surgery. It was hypothesized that hearing loss in the EHF range would be mixed in the initial stages, with recovery of the conductive element over the first three month period so that SNHL remained. It was also expected that stapes surgeries would show higher rates of SNHL than the ossiculoplasty and tympanoplasty surgeries, which were hypothesized to show more of a CHL.

As anticipated, despite improvement to the CF range for all cases except Case B, all four cases demonstrated either a mixed, conductive or sensorineural hearing loss in the EHF range following surgery. The two stapes surgery cases illustrated greater SNHL initially, with partial recovery at three months for both cases, while the tympanoplasty and ossiculoplasty surgery cases exhibited greater CHL, which for one case increased as the post-operative assessments progressed. The following sections will further discuss each of the individual components of hearing loss, along with possible causes.

3.3.1. *Post-operative sensorineural hearing loss*

In all of the four cases, there was at least a slight post-operative SNHL present at one or more of the post-operative assessments. SNHL was more prominent in the initial post-operative assessments for the two stapes surgery participants (Case A and Case C) compared to the tympanoplasty and ossiculoplasty cases (Case B and Case D). Case A showed a significant transient increase in BC thresholds at all frequencies except 16 kHz at the one month post-operative assessment, with slight recovery at three months. As all thresholds were measurable at every pre- and post-operative assessment for this participant, these sensorineural changes to the EHF thresholds were demonstrated clearly. Contrastingly, the pre-operative hearing loss exhibited in Case C prevented seeing the full extent of surgery to EHF thresholds, however, this case also revealed an initial increase of BC thresholds relative to the non-operative ear, with recovery back to pre-operative levels from 12.5 – 11.2 kHz. Despite this recovery, there was a change in the highest measurable BC threshold at three months from 12.5 to 11.2 kHz, indicative of persistent cochlear injury.

In contrast to these two cases, the remaining two participants, Case B and Case D, displayed only small changes to EHF BC thresholds. Despite only small BC increases at the one month assessment for Case B, these changes were not expressed in the non-operative ear, suggestive of slight but existent SNHL. Additionally, the loss of one AC test frequency from 12.5 to 11.2 kHz may too reflect inner ear injury, although it could conversely indicate a change to middle ear transmission characteristics. This participant was the only participant to also show a significant increase in BC thresholds in the CF range, most notably at the lower frequencies of 0.5 – 2 kHz. Case D also illustrated an initial BC increase at the one month assessment, with a change in the highest measurable AC frequency from 14 kHz to 11.2 kHz, which partially recovered to 12.5 at the three month assessment. A change to the highest measurable BC frequency from 16 to 12.5 kHz was also prominent, which fully recovered at the three month post-operative assessment.

The results from the current study were largely in agreement with Babbage (2015), who demonstrated clear post-operative EHF SNHL in three out of four cases. In two of these three stapes cases, an initial increase to BC thresholds was present which persisted at the three month post-operative assessment. An additional participant also had an AC and BC increase of 10 dB HL throughout the EHF range, however pre-operative hearing loss made these results harder to interpret. This is comparable to the two participants in the current study who had undertaken stapes surgery, both of which showed BC threshold increases at the initial post-operative assessment with partial but incomplete recovery at the three month assessment.

Hallmo and Mair (1996) also found a small but significant change to mean thresholds in the range of 8 – 16 kHz three months following unspecified middle ear surgeries, although they argued this was likely due to the placement of the transducer rather than a result of SNHL. However, considering changes were present in the operative ear despite no significant changes in the contralateral ear, as we also found in the present study, it may be that the small changes were indeed representative of cochlear injury. We also found a small change to BC thresholds in Case B and Case D, although this was more distinct at the one month follow up in both cases, in contrast to the three month data collection point utilized in the Hallmo and Mair (1996) study.

Like the present study, several other studies have also exhibited potential cochlear harm through changes to the highest measurable frequency following middle ear surgery. Doménech and Carulla (1988) showed that 67% of participants undergoing stapes surgery had a loss in the highest measurable frequency a few days following surgery, and 83.4% showed a moderate BC hearing loss in the EHF, especially at the frequencies of 11 – 14 kHz and 18 kHz. This is comparable to the current study where Case A and Case C both illustrated an initial deterioration to EHF BC thresholds with partial recovery after three months, however, Doménech and Carulla (1988) did not perform any post-operative testing

past 48 hours, hence it is unknown if recovery of BC thresholds also occurred in their study. Doménech et al. (1989) also found nine participants in a sample of 24 who underwent tympanoplasty surgery had a change in the upper limits of audible frequencies, with four of these considered statistically significant. However, unlike in the present study whereby the tympanoplasty participant (Case B) demonstrated very small BC EHF threshold changes at one month post-operatively, it was found that most of the participants included in the study demonstrated a considerable increase in BC thresholds from 11 – 15 kHz, although the post-operative assessment timing for this was unspecified. Similarly to the previous two reports, Hegewald (1989) also demonstrated a mean change to the highest measurable frequency of an 890 Hz loss at one month following mastoid surgery. Additionally, they also found a statistically significant temporary threshold shift to BC thresholds at 16 kHz within 48 hours following mastoid surgery, which recovered by the three month assessment.

While Doménech and Carulla (1988), Doménech et al. (1989) and Hegewald (1989) studies provided some support that SNHL occurs in at least the initial stages following middle ear surgery, the applicability of the evidence to the current study is restricted by the methodological limitations of the research. Along with the previously discussed research conducted by Hallmo and Mair (1996), the electrostimulation technique that was used in these studies meant only BC thresholds were obtained in the EHF range, therefore it is unknown whether CHL or mixed hearing loss was also apparent in each of the individuals in each study. Thresholds were also unmasked, therefore changes to thresholds reflected only the better hearing ear at the time of testing. In addition to this, the surgeries that were assessed varied in comparison to the surgeries examined in this study. As each surgery utilizes different techniques, procedures and equipment, direct links between the literature and our current study are difficult to make.

As mentioned in Section 1.6.1, there are a number of plausible explanations as to why EHF hearing impairment presents post-operatively. Exposure to harmful noise levels has been suggested and has mixed evidence as a possible cause of SNHL following middle ear surgeries (Baradaranfar et al., 2015; Dalchow et al., 2013; de Zinis et al., 2010; Kylén & Arlinger, 1976; Kylén et al., 1977; Leonettie et al., 2012; Urquhart et al., 1992). Although frequently reported as a cause of SNHL, little research has been undertaken examining the direct relationship between noise levels, time exposure and hearing outcomes in the EHF range. Regardless of this theory, the current study did not record intra-operative drill times or noise levels, and therefore noise exposure as a causation of post-operative SNHL cannot be confirmed in the present series.

Another frequently reported theory is that intra-operative handling of the ossicular chain causes an increase in force transmitted to the cochlea, which may be particularly evident in stapes and ossiculoplasty surgeries, as these involve more direct alterations of the ossicles (Babighian & Albu, 2009; Hallmo & Mair, 1996; Kylén et al., 1980; Mair & Laukli, 1986; Økstad et al., 1988; Palva et al., 1973). Although there is no direct evidence that links ossicular chain manipulations to hearing loss, there is some research to suggest handling of the ossicular chain may result in cochlear injury. For instance, the change in surgery preference from stapedectomy to stapedotomy, which is proposed as requiring less direct manipulation to the ossicular chain (Cheng et al., 2018), along with higher rates of post-operative hearing loss in trainee surgeons (Bergin, 2012), suggests that increasing levels of force exerted on the ossicular chain may result in harm to the cochlea. Additionally, it has been reported that instances of accidental drill contact with the ossicular chain could cause cochlear damage (Banakis Hartl et al., 2017; Gjuric et al., 1997; Jiang et al., 2007; Paparella, 1962), although studies to examine this thus far have involved the use of animals or cadaver participants only. Further research to directly examine contact with the ossicular chain and EHF hearing outcomes may be useful in determining the cause of post-operative SNHL.

Other proposed causes of EHF SNHL include the use of lasers as an alternative to drilling (Arnoldner et al., 2006; Häusler et al., 1999; Jovanovic et al., 2004; Somers et al., 2007), or other less likely occurring phenomenon such as perilymph aspiration (Ikeda et al., 2011), endolymphatic hydrops (Ishai et al., 2016; Shea et al., 1995) or the presumably rare intra-operative complication of perilymph fistulas (Jovanovic et al., 2004; Meldrum & Prinsley, 2016). None of these elements were directly assessed in the present study, and further investigation may be warranted.

3.3.2 *Post-operative conductive hearing loss*

In all four cases, at least a partial EHF CHL manifested in the post-operative stages of testing. The tympanoplasty and ossiculoplasty participants (Case B and Case D, respectively) had a considerably larger conductive element to the EHF hearing loss compared to the two stapes surgery participants, with small changes to BC (± 5 dB HL) and larger increases to AC at post-operative follow ups. For Case D the AC thresholds continued to increase at the three month post-operative assessment, despite recovery of BC thresholds to within ± 5 dB HL of pre-operative levels. As Case B was only examined at the one month post-operative assessment, it is unknown whether AC thresholds also continued to rise.

While the two cases just discussed exhibited increases to AC at the one month and three month follow ups, the two remaining cases, Case A and Case C, demonstrated an overall improvement to AC thresholds over the post-operative course, which decreased more with each post-operative assessment. Conversely, despite improvements to AC, there remained a small conductive element at one month and three months for Case A, while Case C displayed a large conductive element at all frequencies at both the one week and three month assessments.

Mair and Hallmo (1994) similarly found that in 22 myringoplasty surgeries, EHF AC thresholds deteriorated while BC thresholds remained stable between two to 11 months

following surgery, suggestive of CHL through impaired middle ear transmission, rather than SNHL from cochlear damage. They argued this was caused by natural properties of the TM such as the thickness and the shape of the TM being disrupted by the replaced materials. While this study examined myringoplasty surgeries, the results from this study displayed similar results to the tympanoplasty case (Case B) and the ossiculoplasty participant (Case D) in this current study, furthering the hypothesis that myringoplasty, tympanoplasty and ossiculoplasty may result in higher rates of CHL than SNHL than stapes surgery.

In the present investigation we found that CHL became more prominent in the ossiculoplasty and tympanoplasty case as time progressed from the middle ear surgery, although data from the three month post-operative assessment was only available for one of these participants. Contrastingly, Babbage (2015) found that CHL typically resolved in the weeks following surgery. However, the surgeries undertaken in the Babbage (2015) study were mostly stapes surgeries, with only one instance of an ossiculoplasty surgery. Likewise, we also found that CHL in one case of stapes surgery improved after three months (Case A). It may be that CHL does indeed decrease with time as Babbage (2015) suggested, or as demonstrated in this current study it is possible that CHL recovers over time in procedures such as stapedectomy and stapedotomy, but may continue to persist in surgeries such as ossiculoplasty and tympanoplasty. As three month follow up data was only available for the ossiculoplasty participant and not the tympanoplasty participant, unfortunately it is impossible to confirm this theory.

There are currently many theories regarding the origins of EHF CHL from middle ear surgery. It is possible that CHL is caused from permanent changes to the physical characteristics of the middle ear including the mass and stiffness properties, impacting the transmission of high frequency signals to the cochlea. There is mixed evidence supporting the theory that mass alternations of the ossicular chain affect the transmission of signals through the middle ear space (Bance, 2018; Bance et al., 2007; Gan et al., 2001; Goode et al., 1994;

Rosowski and Merchant, 1995), while there is slightly stronger evidence to show that altering the mass of the stapes alone tends to show less impact on hearing outcomes than the incus or malleus (de Bruijn et al., 1999; Bance et al., 2007; Goode et al., 1994; Rosowski and Merchant, 1995). Bance et al. (2007) proposed that prostheses have a different impact in each individual ear, due to anatomical and pathological differences between people. It is unsurprising, given this suggestion, that some cases demonstrate long-term EHF CHL, for instance Case D at the three month post-operative assessment, while others such as Case A do not.

In addition to mass characteristics, alterations to the tension properties of prostheses are also thought to affect sound transmission, with longer prostheses generally resulting in higher tension (Morris et al., 2004; Neudert et al., 2016). It has been suggested that using a low tension prosthesis in middle ear surgery, while providing good hearing outcomes for the lower frequencies in the CFs, may impair high frequency sound transmission to the inner ear. However, while the prosthesis length may have a relationship on transmission mechanisms of high frequencies to the inner ear, there are no intra-operative tests to confirm this, and the present study was therefore unable to examine this factor directly.

In addition to these theories of permanent change to middle ear characteristics, there are also theories that CHL is related to more transient factors which modify the transformer and impedance functions of the middle ear (Robinson & Kasden, 1977) such as the use of packing materials in surgery (Cho et al., 2007). Furthermore, Robinson and Kasden (1977) suggested high frequency CHL in the CF range in 25 stapedectomy surgeries was a consequence of surgical factors such as microhaemorrhage, edema and transudates. This provides an attractive explanation as to why the two stapes cases in the current study revealed a CHL in the initial stages post-operatively, with recovery in the months following as the middle ear healed. However, as Robinson and Kasden (1977) did not assess changes beyond the seven day post-operative period, and examined changes in the CF range only, it is unclear

whether hearing loss was temporary or irreversible, and therefore comparisons to the present investigation are difficult to draw.

3.3.3 *Post-operative ABG changes*

One method that is commonly used to report post-operative surgical success is to examine the size of the ABG postoperatively compared to the pre-operative levels. For the two stapes cases, Case A and Case C, the size of the ABG in the EHF range at the three month post-operative follow up was reduced compared to pre-operative levels. On the other hand, the tympanoplasty case (Case B) and the ossiculoplasty case (Case D) illustrated ABGs in the EHF range that were comparable in size to the pre-operative values at one month post-operatively for Case B, and three months post-operatively for Case D.

A reduction of the ABG can illustrate several outcomes and should be interpreted with caution. The first is that it can represent an improvement to AC thresholds closer to that of stable BC thresholds, reducing the CHL and typically improving hearing outcomes. This is often seen in the CF range in middle ear surgery, where AC thresholds often decrease to meet the BC thresholds (Harder et al., 1982; Kishimoto et al., 2015; Lee et al., 2008; Salmon et al., 2015). However, the opposite effect can also occur, where a reduction to the ABG can occur when BC thresholds deteriorate to approximate the AC thresholds, giving the appearance of a decreased CHL despite the presence of SNHL. Of course, there can also be a combination of the two, where AC thresholds improve as BC deteriorates. What becomes apparent is that there is a risk in reporting the absence of CHL as surgical success, as SNHL can still manifest despite the closure of an ABG. This was indeed exhibited in the present study, for example in Case A, where thresholds from 8 – 12.5 kHz conveyed both SNHL and an improvement to AC thresholds, reducing the size of the ABG from pre-operative levels. This would suggest that iatrogenic cochlear injury is largely responsible for this particular case. Contrastingly, the size of the ABG remained relatively stable from the one week post-operative assessment and the three month follow up for Case C, as both AC and BC thresholds improved at the

same rate from 8 – 11.2 kHz. Given these two instances, it is clear that reporting changes to the ABG may not be the most sensitive tool of measuring surgery success.

3.3.4 *Limitations of the current study*

The major limitation to the current study was the small sample size of four. While the aim of the study was to expand on the works of Babbage (2015) in a larger group of participants, unfortunately only six suitable candidates were recruited for the study, with two of these participants unable to attend post-operative assessments and therefore later excluded from the study. There were also very few participants within each surgical categorization, with only two stapes, one ossiculoplasty and one tympanoplasty surgeries performed. A larger group of participants within each surgical category would have been preferable to draw more distinct conclusions about the features of EHF hearing loss for each surgical type, which is likely to vary given the differing surgical procedures and equipment utilized in each, as discussed in Section 1.4.2.

In addition to this, all four cases failed to attend at least one of the post-operative assessments, meaning it was more difficult to make comparisons between participants at each post-operative assessment. One participant, Case B, attended only one follow up appointment one month post-operatively, meaning it could not be established if hearing impairment was temporary or permanent. Post-operative assessment attendance relied on a number of factors such as the otologist appointment timing and the availability of the equipment, the testing location and of both the participant and the researcher.

Furthermore, if not due to time constraints in the current research, ideally participants would have been tested over a longer period of time to further assess CHL and SNHL over a longer timeframe. It is possible that BC thresholds may recover at a different rate to AC thresholds; as this had never been assessed in any research to our knowledge, long-term

changes to EHF thresholds following middle ear surgery are unknown. Under ideal circumstances, further assessment would have occurred at the six month, one year and two year follow ups.

The inability of the GSI-61 audiometer to provide high levels of masking meant often masking was most likely insufficient to isolate the test ear, most notably at the frequencies of 14 – 16 kHz whereby masking was limited to around 20 dB HL in some cases. This meant that ear-specific BC thresholds may not have been accurate, as thresholds may have been recorded as being better than they actually were. This inability to produce sufficient masking may too have influenced the size of the ABGs that were reported in the current study. If thresholds were indeed worse than what was measured using insufficient masking, this would result in a falsely created ABG, creating the illusion of a CHL instead of the true SNHL.

Another limitation to the current study was adding the correction factors (established in Section 2.2.5) to the EHF thresholds after testing had occurred, due to time constraints. The major implication of this was that BC thresholds were undetermined at the time of testing. This meant that AC masking was at times not provided when interaural attenuation was exceeded between the non-operative ear BC threshold and the operative ear AC threshold, as it would have been had correction factors been applied prior to testing. In these circumstances, the participant may have responded to the pure-tone heard in the non-operative ear, giving falsely improved AC thresholds to the operative ear. Ideally correction factors would have been measured prior to testing the participants in this current study and added to the custom audiometer software to remediate this issue.

Another limitation, which is frequently reported as an issue in PTA testing in cases of bilateral or mixed hearing loss (Lenhardt, Goldstein, & Shulman, 2006), was that adequate levels of masking were not able to be obtained in the non-operative ear without simultaneously overmasking the operative ear. The one month follow up for Case A may demonstrate this phenomenon, whereby the frequencies of 11.2 – 14 kHz were likely overmasked. This may have falsely increased BC thresholds of the operative ear at these

frequencies, as the masking signal may have crossed over to the operative ear. The repercussions of this were that hearing loss was displayed as sensorineural, where it may have been conductive or mixed.

3.3.5 *Directions for future research*

Clearly the most necessary direction for future research would be to gather more EHF data following middle ear surgery in a larger group of participants, as was intended in the current study. In addition, it would be useful to include as many participants as possible with good pre-operative BC thresholds, so that changes to thresholds can be more easily detected than those with elevated thresholds. This is particularly relevant to cases where the highest measurable frequency falls at a frequency below 16 kHz, as the extent of hearing impairment across the entire EHF range is less easily assessed.

The cause of post-operative hearing loss also needs to be examined in future studies. A more direct comparison should be examined between hearing outcomes and surgical factors such as the surgical procedure and the tools and equipment used. Comparing hearing outcomes across multiple middle ear surgical types such as mastoidectomy and myringoplasty surgeries may too provide insight to the true cause of EHF hearing impairment following middle ear surgery. Collecting more data across these areas may provide further information to the broad site of lesion affected, distinguishing between damage to the middle ear and the inner ear, or both. This may allow new surgical techniques and equipment to be developed, such as the promising use of pharmacological agents such as corticosteroids (Bird & Bergin, 2018) to minimize further damage in future procedures, and to improve hearing outcomes in the EHF range.

There may also be benefit in researching further methods of collecting EHF data. Development of new transducers capable of measuring EHF BC data could provide use in determining accurate EHF thresholds. The current accessibility of the TEAC HP-F100

transducer utilized in this study is very limited as it is no longer commercially available, and many modifications were necessary to make it appropriate for clinical testing, as outlined in Section 2.1.2.1. Further research into new EHF BC transducers for clinical use is therefore warranted.

3.4 Conclusions

This study confirms the results of the Babbage (2015) study that EHF hearing loss following middle ear surgery is a frequently occurring phenomenon and is comprised of sensorineural and conductive elements, which change over a course of at least three months. Four cases are presented, two of which demonstrate a distinct deterioration of BC EHF thresholds in the early post-operative phases, which partially recover by three months post-operatively. The remaining two cases indicate an increase of AC thresholds despite little change to BC thresholds at the one month post-operative assessment, and for one case the three month assessment also. It appears there may be higher rates of SNHL in patients undertaking stapes surgery compared to ossiculoplasty and tympanoplasty surgical procedures, which appear to display more of a conductive element. Further research with more participants over a longer period of time will be of benefit to assess the true components of EHF hearing impairment in tympanoplasty, ossiculoplasty and stapedotomy surgeries.

4.0 Determining EHF BC thresholds in patients with previously documented EHF AC hearing loss

The previous section aimed to explore changes to EHF thresholds over a three month period following middle ear surgery. The current section aimed to assess more long-term changes to AC EHF thresholds in patients from the Babbage (2015) study with previously documented thresholds both before and up to two years after middle ear surgery. An additional aim was to determine masked BC thresholds in the EHF range in the same population to establish the type of existing hearing loss. It was anticipated that there would be a SNHL evident in the EHF range, with a potential conductive element.

4.1 Method

4.1.1 Participants

The current study was performed in accordance with the Department of Otolaryngology Head and Neck Surgery, Christchurch Public Hospital, and one surgeon working within the private sector in Christchurch. Patients that were included in this phase of the study had previously undergone primary or revision middle ear surgery within the last 10 years. Participants were considered eligible to be included in the study if they met the following criteria:

- A. At or above the age of 16 years at the time of their surgery
- B. Undertaken either primary or revision stapedectomy/stapedotomy, tympanoplasty or ossiculoplasty within the last 10 years
- C. Previously documented and measurable pre-operative bilateral AC thresholds up to at least 10 kHz or higher
- D. Post-operative bilateral AC thresholds up to at least 10 kHz or higher
- E. Average pre-operative BC thresholds at 0.5, 1 and 2 kHz no more than 50 dB HL
- F. No other significant disorders resulting in an auditory or vestibular impairment

Eight participants identified by one otologist were eligible for this phase of testing, and were sent a letter inviting them to voluntarily participate in the study. All participants who agreed to participate were given an information sheet (Appendix 1c) about the study by the otologist, and were required to give written consent (Appendix 2) before commencing testing. Demographic information that was collected for the study included patient age, sex, otologic history and symptoms, and surgical information.

For this phase of testing, based on the above criteria two participants were recruited and agreed to participate. Both participants were female, and the ages ranged from 64 to 65 years old ($M = 64.5$ years, $SD = 0.71$).

Table 5. Participant characteristics.

Participant	Age	Sex	Surgery type	Operative ear
1	65	F	Stapedotomy	Right ear
2	64	F	Stapedotomy	Left ear

4.1.2 Equipment

Assessment was performed at the University of Canterbury Speech and Hearing Clinics, in a sound treated room as required by International Organization for Standardization [ISO] 8253-1 (2010). A calibrated GSI-61 diagnostic audiometer (Grason-Stadler, Eden Prairie, MN) was used to assess PTA in the CF range (0.25 – 8 kHz). ER-3A insert earphones (Etymotic Research Inc., Elk Grove Village, IL) were used to present AC stimuli. Where insert earphones were contraindicated, stimuli were also presented through TDH-39 supra-aural headphones (Telephonics Corporation, Farmingdale, NY). BC stimuli (0.5 – 4 kHz) were presented via a Radioear B-71 (Radioear Corporation, New Eagle, PA) BC transducer which was placed on the mastoid.

AC stimuli in the EHF range (8 – 16 kHz) were also presented using the same GSI-61 audiometer. Sennheiser HDA 200 circumaural headphones (Sennheiser electronic GmbH &

Co., Wennebostel, Germany) were used to present AC stimuli in this frequency range.

Computer based custom audiometer software was utilised for BC EHF stimuli, written using LabVIEW 2012 (National Instruments, Austin, TX). BC stimuli were presented via a TEAC HP-F100 BC transducer (TEAC, Tokyo, Japan), modified in a previous study for the purpose of audiometric testing (Babbage, 2015). This device was connected to a MOTU external multi-channel sound card (MOTU, Cambridge, MA), which was connected to a laptop via USB to produce the pure-tone sound stimuli. EHF masking from 8 – 16 kHz was presented through the Sennheiser HDA 200 circumaural headphones using the GSI-61 audiometer.

4.1.3 Procedure

4.1.3.1 General procedure

For all eligible participants, only one assessment appointment was required as these participants already had documented pre-operative and post-operative EHF AC thresholds from a previous study (Babbage, 2015). During this appointment, there was an otoscopic examination before bilateral AC and BC audiometry of both conventional pure-tone frequencies and the EHF range.

Participants were informed they would hear a range of tones of varying pitches and volumes, and were instructed to press a response button whenever they heard a tone. “No response” was recorded on the audiogram when the participant did not press the button after two repetitions at the limit of the audiometer for any given frequency.

4.1.3.2 Conventional frequency pure-tone audiometry

Following otoscopic examination, CF thresholds were recorded in response to continuous pure-tone stimuli using the Modified Hughson-Westlake technique of 5 dB HL step increments (Carhart & Jerger, 1959). For AC, thresholds at octave frequencies from 0.25 kHz - 8 kHz, and at 3 kHz, were assessed in both ears. When interaural attenuation values, as outlined by Katz et al. (2015), between the AC thresholds of the test ear and the AC or BC

thresholds of the non-test ear were exceeded for any given frequency or transducer, narrow-band masking noise was presented to the contralateral ear using the appropriate transducer.

For BC, the transducer was positioned on the mastoid. Thresholds were measured at octave frequencies from 0.5 - 4 kHz, and in addition at 3 kHz. Narrowband masking noise was presented in the non-test ear during all BC testing in the CF range. All masking used a step masking technique described by Yacullo (1996).

4.1.3.3 Extended high frequency pure-tone audiometry

Using the circumaural headphones, in both ears AC stimuli was presented at 1/6th octave frequencies from 8 - 16 kHz. The Modified Hughson-Westlake technique (Carhart & Jerger, 1959) was performed using 5 dB HL step increments to measure thresholds in response to continuous pure-tone stimuli. A step masking technique was applied to present narrowband masking noise via the Sennheiser HDA 200 headphones if the AC thresholds in the test ear and the AC or BC thresholds in the non-test ear differed by the conservative interaural attenuation value of 40 dB HL, based on research conducted by Brännström and Lantz (2010). Due to the reduced dynamic range of the audiometer in the EHF range, where adequate masking could not be obtained as a result of reaching the output limits of the audiometer, an asterisk was marked on the audiogram to indicate this.

For BC stimuli, the TEAC HP-F100 bone vibrator was positioned on the forehead as close to the midline as possible. Likewise with EHF AC, stimuli were presented at 1/6th octave frequencies from 8 - 16 kHz in both ears. Contralateral EHF narrowband masking was always applied to the non-test ear at 30 dB above the AC thresholds for that same ear at any given frequency. Where adequate masking levels were not presented to the non-test ear, an asterisk was written next to the test frequency it applied to on the audiogram.

4.1.4 *Data analysis*

Due to the low number of participants recruited, it was decided to use a case study approach to analyse the current data. Data from the Babbage (2015) was utilised to assess changes in AC thresholds from 0.25 – 16 kHz and BC thresholds from 0.5 – 4 kHz in both the operated and non-operated ears, by subtracting the post-operative threshold from the pre-operative threshold. Positive numbers indicated thresholds improvements, whereas negative numbers indicated an increase or worsening of hearing thresholds. In instances where hearing thresholds could not be measured before the limits of the audiometer were reached, the threshold was determined as 5 dB HL above the output level for that particular frequency for calculation purposes. The number of measurable test frequencies lost was also calculated, for example, if a threshold was measurable at 16 kHz before surgery but the highest threshold was 14 kHz post-operatively, this was defined as one test frequency lost.

In addition to this, EHF BC thresholds from 8 – 16 kHz were obtained in the operative-ear and the non-operative ear, and the ABG was established by calculating the difference between AC and BC thresholds at the relevant frequency, Deviations from 0 dB HL indicated ABGs, with bigger deviations from 0 dB HL indicating larger ABGs. ABGs of 15 dB HL or more were defined as significant.

4.2 *Results*

4.2.1 *Case E*

Case E was a 65 year old woman who had a left stapedotomy procedure in 2006 and a right laser stapedotomy procedure in 2013 following a clinical diagnosis of slowly progressive bilateral otosclerosis. Although both ears underwent surgery, for the purposes of this study the ear undergoing the most recent procedure was referred to as the operative ear and the ear undergoing earlier surgery as the non-operative ear. Full surgical details are provided in Babbage (2015).

Pre-operative data, displayed in Figure 27, was collected for the Babbage (2015) study before the right stapedotomy in 2013, with no preoperative EHF data available for the previous left stapes surgery. Pre-operative data revealed a mixed hearing loss that was mild sloping to moderate, rising back to mild at 4 kHz and again sloping in the EHF to a severe hearing loss. Post-operative data was collected at one week, one month, three months, six months and one year following the surgery for the Babbage (2015) study. Only AC thresholds were measured in the EHF region, with no BC data available.

4.2.1.1 Changes to pure-tone thresholds five years following surgery

Data for the current study was collected five years following the right stapedotomy procedure. As demonstrated in Figure 27 and 28, in contrast to pre-operative data AC thresholds recorded 5 years after surgery had significantly improved at all frequencies in the CF range, with maximum improvement of 30 dB HL at 1 and 3 kHz. AC thresholds had, on average, either slightly improved (10 dB HL at 0.25 kHz and 15 dB HL at 3 kHz) or stayed stable in the CF range from the most recent post-operative assessment from the Babbage (2015) study, taken at one year following surgery. BC thresholds in the CF range at five years revealed an improvement ranging from 5 dB HL at 0.5 kHz to a maximum of 20 dB HL at 2 kHz compared to pre-operative data. All BC thresholds were within 5 dB HL of the one year follow up data, reflecting stable BC thresholds in the CF range over a four year period.

In the EHF region, there was an overall deterioration to all AC EHF from 8 – 12.5 kHz at the five year follow up compared to pre-operative data, with a deterioration of thresholds also evident from 10 kHz onwards relative to the one year assessment. Thresholds at 14 and 16 kHz remained unmeasurable at all pre-operative and post-operative assessments. There were also changes to the highest measurable frequency in the operative ear, from 12.5 kHz pre-operatively and at the one year follow up to 10 kHz at the five year post-operative mark. The contralateral ear exhibited no significant changes to EHF AC thresholds at any assessment period.

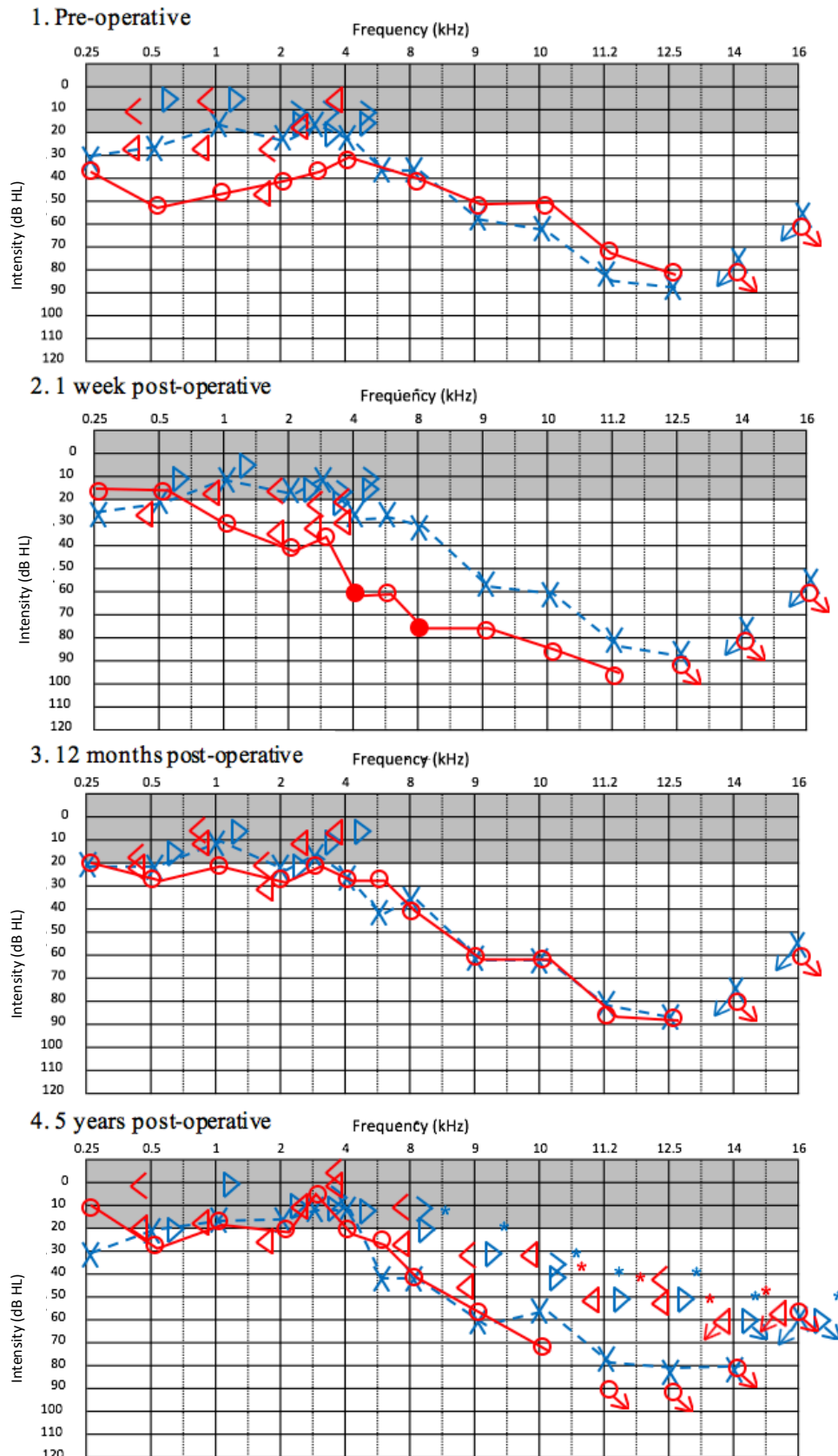


Figure 27. Audiograms for participant E. The top three audiograms display the pre-operative and one week and one year post-operative audiograms collected in the Babbage (2015) study, while the bottom audiogram displays data collected from the current study. Instances of potentially insufficient masking levels are indicated by asterisks.

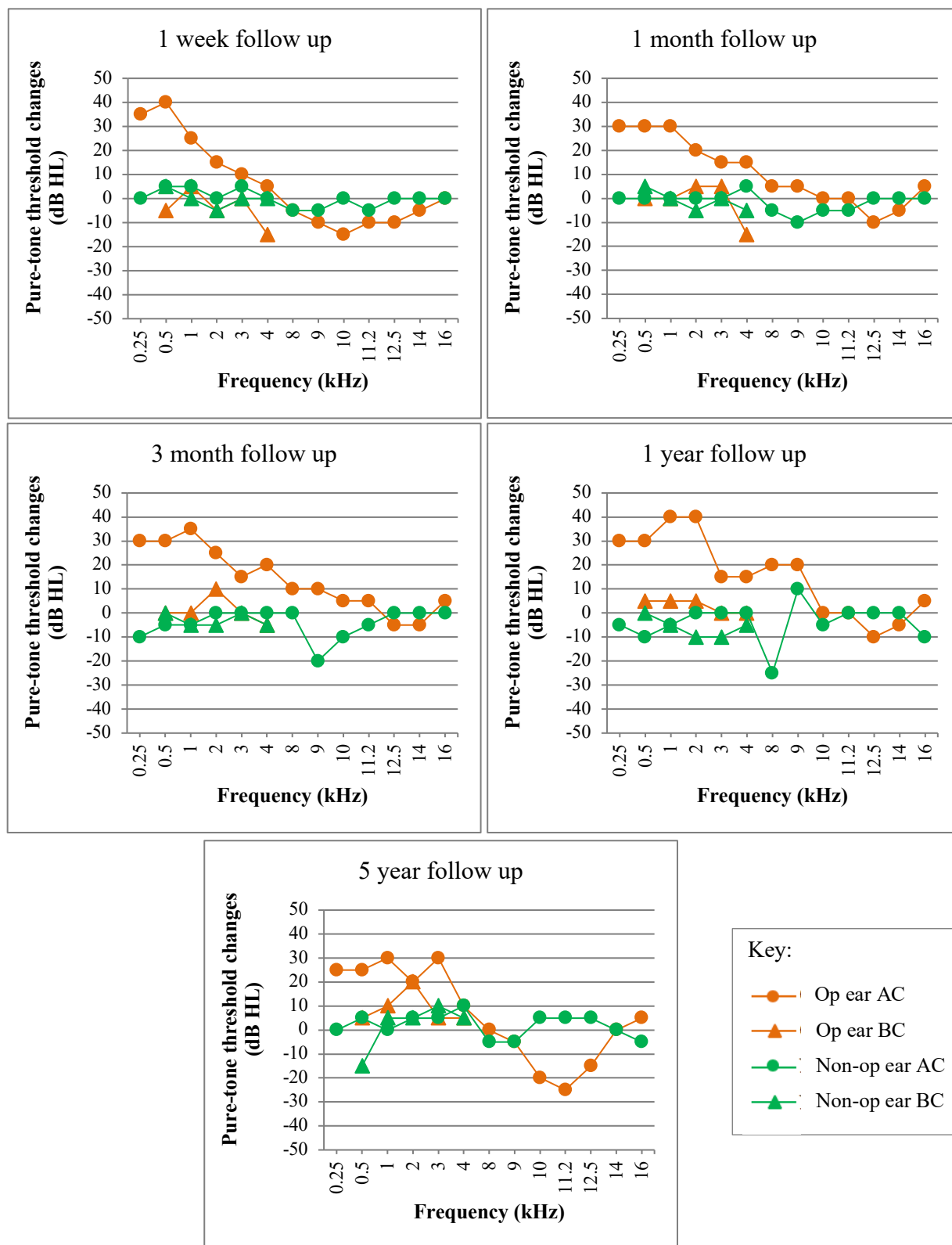


Figure 28. Changes in air conduction and bone conduction thresholds relative to preoperative thresholds for participant E in both the operated ear and the non-operated ear from the pre-operative assessment. The four top charts demonstrate some of the data collected from the Babbage (2015) study, whereas the bottom chart illustrates data collected in the current study. Improvements in thresholds are indicated by positive numbers, whereas negative numbers indicate an increase in thresholds.

EHF BC data at the five year follow up as displayed in Figure 29 revealed the presence of a mixed hearing loss at all frequencies from 4 - 16 kHz in the operative ear. The ABG size ranged from 12.4 at 9 kHz to a maximum of 44.1 at 11 kHz, although the ABG scale could be overestimated due to masking limits from 11.2 kHz onwards. The non-test ear also showed a significant ABG from 8 – 16 kHz. BC thresholds were comparable in both ears. As there were no BC results to compare to at pre-operative and all other post-operative assessments, it cannot be determined whether any EHF SNHL was incurred from the stapedotomy.

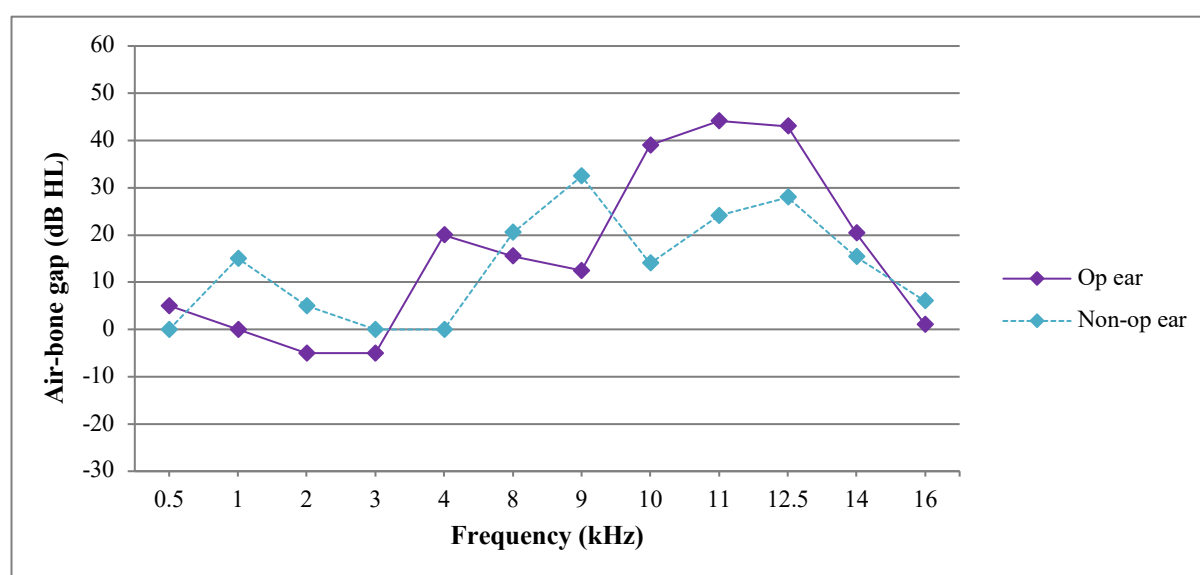


Figure 29. Differences between air conduction and bone conduction results for participant E in the operative ear and the non-operative at the five year follow up. Larger numbers indicate a larger air-bone gap, with proximity to 0 indicating equal air conduction and bone conduction thresholds.

4.2.2 Case F

Case F was a 64 year old woman who, following a clinical diagnosis of otosclerosis, had a right stapedotomy in 2010 and a left laser stapedotomy in 2012. As with Case E discussed in Section 4.2.1, for the purposes of this study the ear undergoing the most recent surgery was referred to as the operative ear and the ear undergoing earlier surgery as the non-operative ear, and further details on the surgical procedure are detailed in Babbage (2015).

Pre-operative data, displayed in Figure 30, was collected for the Babbage (2015) study for the left stapedotomy, with no preoperative EHF data available for the previous right

surgery. Pre-operative data revealed a moderately-severe hearing loss in the CF range that was conductive characteristically in the low frequencies (0.5 – 1 kHz) and mixed in the high frequencies (2 – 4 kHz), sloping to a severe hearing loss in the EHF. Post-operative data was collected at one week, one month, three months, six months, one year and two years following the procedure as outlined in the Babbage (2015) study. BC thresholds in the EHF were not assessed during this period, but were measured six years post-operatively.

4.2.2.1 Changes to pure-tone thresholds six years following surgery

For the current investigation, data was collected six years following the left stapes procedure. At six years, there was an overall improvement from pre-operative AC thresholds in the operative ear and an increase to AC thresholds in the non-operative ear. While AC thresholds in the CF range improved at post-operative assessments up to two years, an increase in thresholds relative to the final early post-operative assessment was recorded at six years, as demonstrated in Figure 31. CF BC thresholds had remained stable at the two year follow up from pre-operative data, yet deteriorated at all frequencies from 0.5 – 4 kHz at the six year follow up. The exception to this was at 3 kHz, which remained the same as pre-operative levels. At the six year assessment, the non-operative ear demonstrated an increase in CF BC thresholds ranging from 10 - 20 dB HL relative to pre-operative data, and an increase of 5 - 10 dB HL at all CFs aside from 3 kHz compared to the two year data.

In the EHF range, compared to pre-operative levels most AC thresholds improved slightly in the operative ear at the two year post-operative assessment, with a maximum decrease of 10 dB HL at 10 kHz, and further improvement ranging from 5 - 15 dB HL at the six year follow up from 9 – 12.5 kHz. In the non-operative ear, AC thresholds deteriorated up to the two year assessment, and again increased further at the six year follow up at all frequencies. Despite improvements to AC thresholds from 8 – 12.5 kHz, there was a decrease in the highest measurable frequency in the operative ear from 14 kHz pre-operatively to 12.5 kHz post-operatively, which was evident across all post-operative testing.

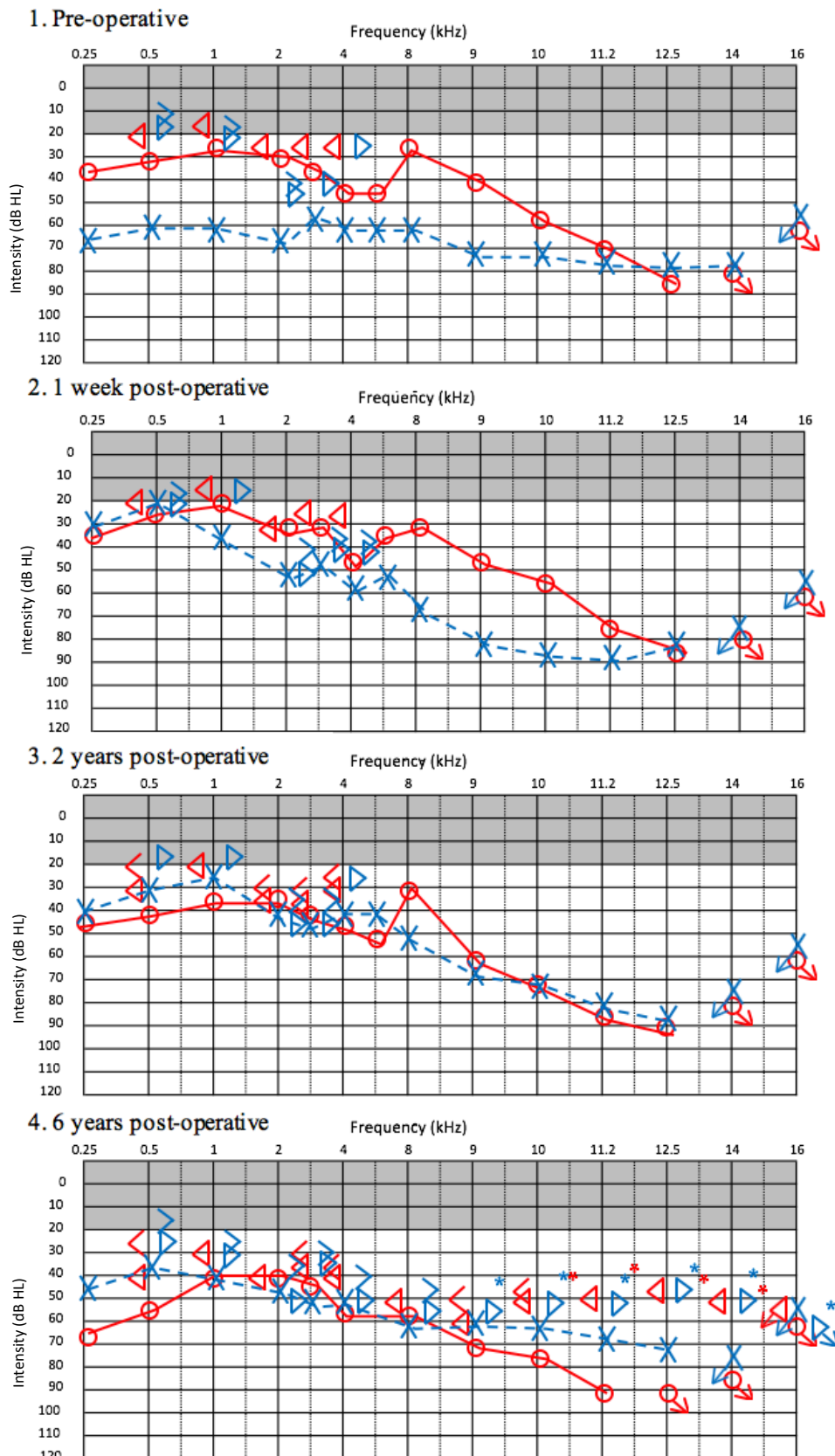


Figure 30. Audiograms for participant F. The top three audiograms display the pre-operative and one week and two year post-operative audiograms collected in the Babbage (2015) study, while the bottom audiogram displays data collected from the current study. Instances of potentially insufficient masking levels are indicated by asterisks.

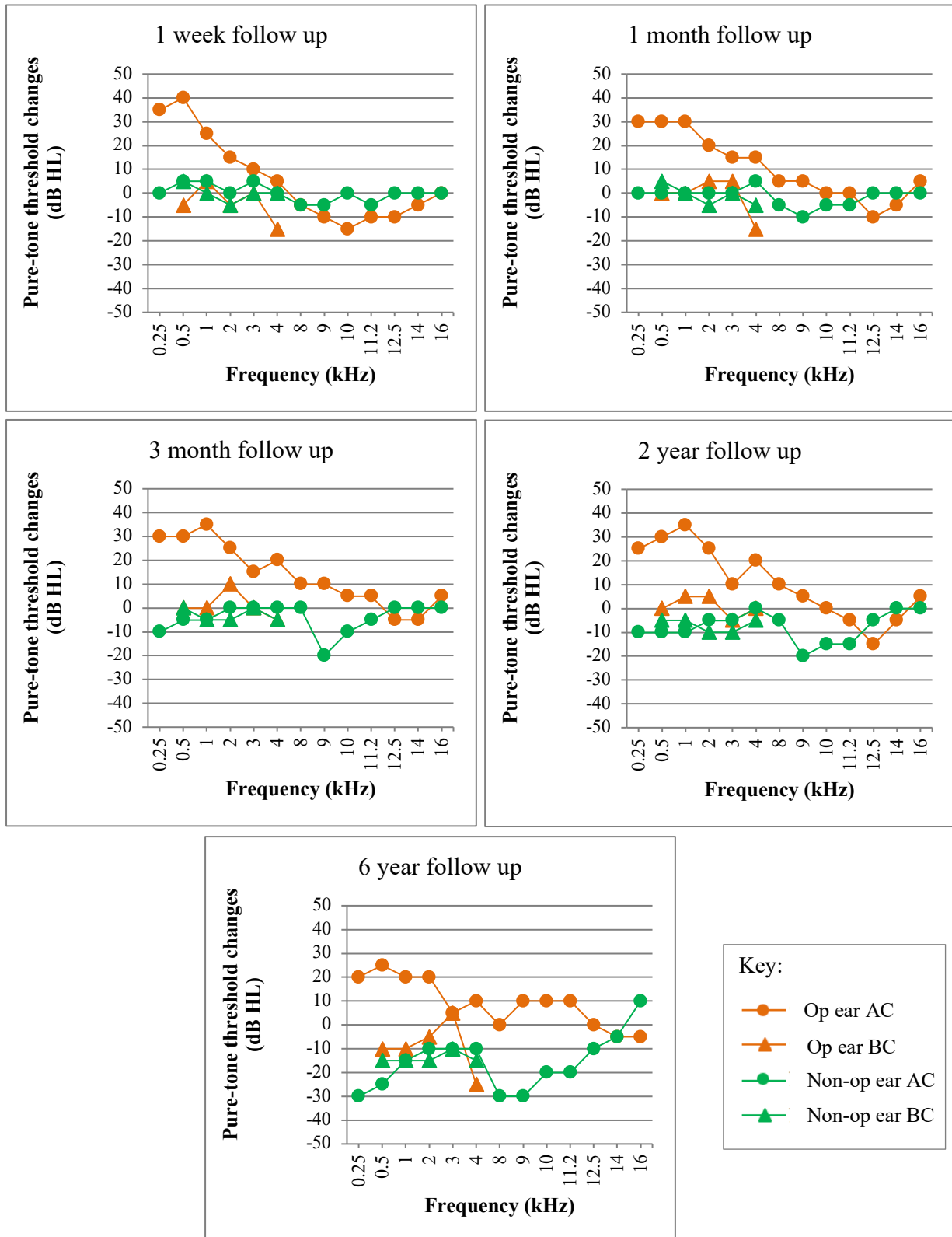


Figure 31. Changes in air conduction and bone conduction thresholds relative to pre-operative thresholds for participant F in both the operated ear and the non-operated ear from the pre-operative assessment. The four top charts demonstrate some of the data collected from the Babbage (2015) study, whereas the bottom chart illustrates data collected in the current study. Improvements in thresholds are indicated by positive numbers, whereas negative numbers indicate an increase in thresholds.

BC data at the six year follow up as displayed in Figure 30 revealed a mixed EHF hearing loss with a significant ABG at the frequencies of 11.2 – 14 kHz in the operative ear (see Figure 32). The non-operative ear also demonstrated a mixed loss with a significant ABG from 9 – 14 kHz, ranging in size from 17.4 – 40.4 dB HL. Only one frequency, 16 kHz, was unmeasurable at the output limits of the audiometer (60 dB HL for the operative ear and 55 dB HL for the non-operative ear). BC thresholds and thus the sensorineural component of the hearing loss appeared similar in both ears, however true thresholds may be higher in one or both ears given that insufficient masking noise was available at most test frequencies. As with Case E, unfortunately there were no other BC data in the EHF to compare to at any other assessment, therefore sensorineural changes could not be examined.

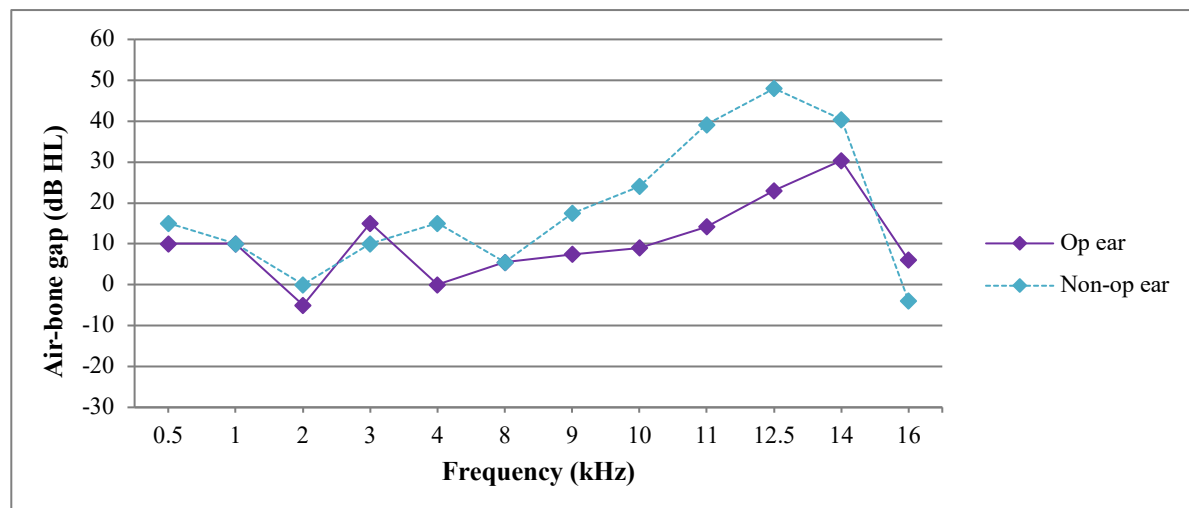


Figure 32. Differences between air conduction and bone conduction results for participant F in the operative ear and the non-operative at the six year follow up. Larger numbers indicate a larger air-bone gap, with proximity to 0 indicating equal air conduction and bone conduction thresholds.

4.3 Discussion

The main aim of the present research was to assess long term changes to EHF thresholds following middle ear surgery. As discussed in Section 1.5.2.2, currently there is very limited data assessing masked BC thresholds following middle ear surgery, and how these change over the post-operative period (Babbage, 2015). Using the calibrated TEAC HP-F100 BC transducer described in Section 2.0, BC thresholds were established in the EHF range for the first time in two participants with previously documented EHF AC thresholds.

As anticipated, it was demonstrated that a SNHL with a conductive element was evident in both cases. However, as BC EHF thresholds were only collected for the five and six year follow up assessments, the presence and extent of SNHL and CHL prior to surgery was unknown, as were early post-operative changes.

4.3.1 *Long-term changes to EHF hearing acuity*

Both participants demonstrated changes to hearing thresholds in the operative ear over the post-operative course. For Case E, compared to pre-operative audiometry there was an overall increase in AC EHF thresholds five years following stapes surgery despite vast improvements in the CF range from pre-operative levels. These AC results had remained relatively stable since the one year follow up data collected in the Babbage (2015) study, although there was a reduction in the highest measurable frequency from 14 kHz pre-operatively to 10 kHz at the five year mark. BC EHF data revealed a mixed hearing loss that was more conductive than sensorineural, with a significant ABG at all frequencies in the EHF, with the exception of 9 kHz in the operative ear. The other participant, Case F, contrastingly demonstrated an overall improvement in AC thresholds from pre-operative levels to both the CF and EHF range at the six year follow up assessment. Initially, at the one week post-operative assessment there was an increase in AC thresholds within the EHF range, which gradually recovered by the six year follow up. BC EHF data also revealed a mixed hearing loss, which appeared to have a greater sensorineural component from 8 – 10 kHz in the operative ear. There was a significant ABG from 11.2 kHz onwards, indicating a large conductive element. It should be noted that despite significant ABGs, for both participants possible insufficient masking levels from 11.2 kHz onwards may have falsely increased the ABG compared to its true value, similarly to the previously discussed cases in Section 3.3.4.

The AC data indicates at least partial deterioration of EHF in early post-operative periods, with an eventual improvement for one participant despite a long term deterioration in

EHFs for the other participant. This is in agreement with previous evidence such as Laukli and Mair (1985), who found a deterioration in EHF AC thresholds in one individual undergoing stapes surgery and no changes to EHF thresholds in another, although the post-operative assessment timing was not specified, hence long-term changes were unknown. Additionally, Babbage (2015) demonstrated long-term changes to EHF thresholds following stapedectomy surgery, with 50% of participants exhibiting a residual hearing loss at the one year follow up. It was interesting to note that post-operative hearing outcomes between the two participants in this study differed significantly, despite the many similarities between the participants, including sex, age, a clinical diagnosis of otosclerosis, previous stapedotomy surgery in the contralateral ear and the same type of surgical procedure (stapedotomy surgery) for the current study.

To our knowledge, masked EHF BC thresholds have only been examined in the short-term following middle ear surgery, up to three months (Babbage, 2015). The current study was therefore the first to examine long-term masked EHF BC thresholds following stapes surgery. Despite this preliminary data, as no EHF BC data was available for any other assessment other than the five year follow up for Case E, and the six year assessment for Case F, it is unclear how BC thresholds in the EHF's changed over time in the earlier post-operative stages. Additionally, it was unknown what types of hearing loss were apparent prior to surgery and how this changed over the post-operative course, and what the effect of both participant's first stapedotomy surgeries had on hearing thresholds prior to the pre-operative data from the Babbage (2015) study. Further research is required to assess this in further detail.

4.3.2 *Possible causes of long-term EHF mixed hearing loss*

There are several mechanisms that could have caused the mixed EHF hearing loss that was exhibited in both participants. For the operative ear in Case E and the non-operative ear in Case F, the persistent post-operative deteriorations in AC hearing acuity at the five and six

year follow up relative to the one and two year follow ups could be suggestive of middle ear pathology recurrence. As Schmid and Häusler (2009) discussed, on occasion conductive hearing loss recurs following stapes surgery despite initial favorable gains to hearing. Prosthesis lateralization, partial or total necrosis of the incus, re-ossification of the stapes footplate and a loosening of the loop on the incus were listed as possible causes of recurrent conductive hearing loss, whereby revision stapes surgery may be indicated to restore hearing. As both cases had previously undergone stapes surgery, either or both ears could have been affected by this phenomenon over time.

As several years have passed since the initial pre-operative and post-operative EHF hearing assessments for both participants, another plausible explanation for the hearing loss at the five and six year follow ups is that the AC changes could be a result of environmental or ototoxic exposure (Dieroff, 1982; Fausti et al., 1981; Fausti et al., 1994; Mehrpavar et al., 2014; Rodríguez Valiente, 2016; Fausti et al., 1994), or from the normal aging process. Hearing loss typically manifests in the high frequencies first due to damage to the basal end of the cochlea (Gacek & Schuknecht, 1969; Wiley et al., 1998), before extending to the lower frequencies as damage occurs towards the apex of the cochlea. With evidence to suggest that non-responses within the EHF range become more frequent in individuals over the age of 50 (Hallmo, Sundby, & Mair, 1994; Osterhammel & Osterhammel, 1979), this may provide an explanation as to why there were changes to the highest measurable frequencies at the five and six year assessment relative to the one and two year assessments for both participants, as at the time of the study they were aged 65 and 64 years old, respectively. Contradictorily, for Case E the non-operative ear did not exhibit any significant changes to AC EHF thresholds at any post-operative assessment, nor did the operative ear for Case F. As the natural aging process, ototoxicity and environmental exposure typically affects both ears equally, the asymmetrical nature of changes between ears for both participants could be indicative that worsening of AC thresholds was caused by other factors.

As mentioned previously, the previous surgeries for both participants may have resulted in similar injuries to each ear. Sperling, Sury, Gordon, and Cox (2013) suggested that patients who had undergone stapes procedures had a long-term deterioration of AC and BC thresholds at a faster rate than control patients, which may be reflective of increased fragility of the cochlea following middle ear surgery. Individual intra-operative factors such as equipment and surgical technique may explain differences in hearing outcomes between the ears. Conversely, the contralateral ear may too have suffered cochlear injury during the most recent stapedotomy procedures, although this may be unlikely considering the results from Section 3.2, whereby each case demonstrated significant EHF hearing loss in the operative ear with minimal changes to the contralateral ear. This is in agreement with work such as Baradaranfar (2015), who found the small amount of contralateral SNHL that occurred following mastoidectomy procedures was reversible within 72 hours.

In addition, the presence of a mixed hearing loss could also have been a reflection of masking limitations. As discussed in Section 3.3.4, masking may not have been sufficient at many of the test frequencies, given the output limitations of the audiometer. This may have resulted in thresholds being worse than what was measured, creating a false ABG.

4.3.3 *Study limitations*

Similarly to Section 3.3.4, the major limitation to the present study was of course the small sample size of two, both of which were around the same age (65 and 64, respectively) and were the same sex (female). Therefore, conclusions that are generalizable to the wider population are unable to be made with the limited information from the two cases.

Additionally, as discussed in the previous section interpretation of results was made even more challenging as no BC threshold data was available for the participants at the pre-operative and other post-operative assessments. As it is unknown what the BC thresholds were prior to surgery, it is undetermined what changes occurred after surgery and whether

changes were transient or permanent. Despite this, valuable information was still obtained showing that SNHL in the EHF range can be evident several years following stapes surgeries.

In addition to this, as discussed in the previous sections both participants had previously had an additional stapedotomy procedure in the contralateral ear, however as these surgeries were undertaken several years prior to the Babbage (2015) study and this current study, EHF threshold data for this period is unavailable. Due to this, it is impossible to determine how much CHL in the EHF range was evident prior to the initial surgeries, and how this changed with the two stapes surgeries for each participant.

Furthermore, as described previously in Section 3.3.4, the small dynamic range of the audiometers presented as a limitation when collecting ear-specific thresholds, most considerably when obtaining masked information for each ear. As previously mentioned, probable insufficient masking for some frequencies meant CHL may have been overestimated or SNHL underestimated in both cases. Further research would benefit from utilizing an audiometer with an increased dynamic range to avoid this in future.

4.4 Conclusions

This small study assessed long-term changes to AC thresholds in the EHF range and established BC thresholds for the first time in individuals with previously documented pre-operative and post-operative AC EHF data. Both cases demonstrated sensorineural and conductive components to post-operative hearing loss collected five and six year after stapes surgeries, however it is unknown how these BC thresholds differed from pre-operative and early post-operative BC thresholds. Further assessment examining long-term changes in other procedures such as stapedotomy, ossiculoplasty and tympanoplasty surgeries is necessary to assist in determining the origins of post-operative hearing loss.

5.0 Summary and conclusions

The overall aim of this thesis was to explore the features of EHF hearing loss before and after middle ear surgery; to determine short term and long term changes to hearing acuity; and to address gaps in the literature regarding BC threshold collection in middle ear surgery participants longitudinally. The following sections will give a brief summary of the results of each of the three studies conducted for the current thesis, from Section 2.0, 3.0 and 4.0, respectively.

5.1 *Calibration of the TEAC HP-F100 transducer*

Updated correction factors using the real-ear technique are presented in this study for the modified TEAC HP-F100 transducer, to apply to uncalibrated EHF BC data. This transducer has been previously described and utilized by Popelka et al. (2010) and Babbage (2015) as a reliable and clinically valid method of measuring BC thresholds in the EHF range. Operating on the assumption that AC and BC thresholds in the EHF range are equal, correction factors were calculated and deemed appropriate to use for testing participants undergoing middle ear surgery, as described in the following section.

5.2 *Measuring changes to EHF hearing acuity following middle ear surgery*

This study explored the relationship between middle ear surgery and hearing acuity over the three month post-operative time course, measured using AC and BC EHF audiometry based on the pilot study described by Babbage (2015). EHF hearing loss is demonstrated in all four cases assessed, all revealing both sensorineural and conductive components. The two stapedotomy cases show higher rates of SNHL in the early post-operative stages, with partial but incomplete recovery of BC thresholds at the three month post-operative assessment. Deterioration of BC thresholds in stapes surgeries reflects iatrogenic cochlear injury through potential causes such as exposure to intra-operative noise or excessive force transmission to the cochlea from direct manipulations to the ossicular

chain, among others. The remaining two cases included in the study, one tympanoplasty and one ossiculoplasty, showcase a large conductive element in early post-operative stages, with increasing AC thresholds in one participant at the three month assessment. Potential causes of early post-operative hearing loss may be reflective of more transient causes such as from edema, microhemorrhage, transudates or packing materials, while changes at the three month assessment may suggest a more permanent change to the physical characteristics of the middle ear space which impact how sound is transmitted through to the inner ear. Differences between the hearing loss incurred through the stapes surgeries and tympanoplasty and ossiculoplasty surgeries are likely due to the varying surgical procedures, techniques and equipment utilized in each.

5.3 *Establishing EHF BC thresholds in patients with previously documented EHF AC thresholds*

Long-term changes to EHF AC thresholds are presented in two cases of stapedotomy patients who have previously documented AC EHF thresholds from a study conducted by Babbage (2015). EHF BC thresholds are also demonstrated for these participants at five years post-operatively for one participant and six years post-operatively for the other, in an attempt to discover the nature of post-operative EHF hearing loss. Both participants reveal a long-term EHF hearing loss which has both conductive and sensorineural elements. As several years have passed since the initial collection of AC EHF data, it is unknown if changes described in this study are an accurate representation of surgical outcomes, or if other factors such as pathological changes or post-operative cochlear fragility have caused the long-term hearing loss. It is also unknown how BC hearing acuity changed within the first few years following surgery, as this data was not collected at the time. Nevertheless, preliminary evidence presented here supports the notion that stapedotomy surgery may create permanent, irreversible changes to hearing in the EHF region.

5.4 *Directions for future research*

Many areas from the current study will benefit from further exploration. The development and standardisation of new audiometers and transducers that are more easily accessible than the TEAC HP-F100 will provide use clinically in assessing changes in hearing from middle ear surgery. As the current thesis determined transducer calibration in a group of participants with normal otologic function, based on the assumption that AC and BC thresholds are equal in the EHF, assessing normative BC EHF data in a larger group of participants may provide benefit in validating this claim. Furthermore, given that the mechanisms of EHF transmission through the middle ear space are currently poorly understood even in normal hearing participants, further investigations into ossicular motions in response to high frequencies in both normal and pathological ears may provide use when designing and implementing prostheses that transmit high frequencies to the inner ear more effectively.

The development of intra-operative monitoring of EHF BC thresholds will also provide useful benefits in preventing injury to the cochlea and to guide surgeons on surgical manipulations and manoeuvres. Directly assessing the relationship between hearing outcomes in the post-operative stages and surgical factors such as techniques and equipment will provide valuable information to surgeons in establishing procedures to intra-operatively preserve cochlear function as much as possible.

In addition to this, continued research into the effects of EHF hearing loss on auditory performance may be of clinical use in improving hearing function. Determining the usefulness of EHF stimuli for areas such as speech understanding, sound localization and music perception may assist in the development of new methods to alleviate consequences of EHF hearing loss, such as extending frequency bandwidths in hearing aids.

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Appendices

Appendix 1a. Information sheet for participants in the transducer calibration study



Department of Communication Disorders
Email: monique.howey@pg.canterbury.ac.nz
13.06.18

Changes in Extended High Frequency Hearing Impairment Following Middle Ear Surgery

Information Sheet

My name is Monique Howey and I am the primary researcher in a study assessing new techniques for measuring changes in hearing sensitivity in the high frequency range. Your participation in this study is entirely voluntary (your choice).

Typically a hearing test assesses your hearing ability at the frequencies (pitches) that are most important for understanding speech. However, sometimes testing higher frequency hearing can allow us to detect early damage to the inner ear (cochlea) compared to when we test the standard frequencies. For example, hearing may become worse at higher frequencies first following exposure to loud sounds, or from some chemotherapy drugs.

To test the hearing sensitivity of the inner ear at the higher frequencies, there is a new device that has been developed which gently vibrates the bone, sending sounds directly to the inner ear. We would like to obtain data using this new device to compare it to the use of standard headphones only. This information will allow us to set-up the device so that we can accurately measure high frequency hearing abilities in people with or without middle ear problems, such as glue ear.

If you choose to take part in this study, your participation in this project would involve two parts. The first part of the study will involve checking your ears for any middle ear problems by performing a brief pressure test of the eardrum and testing your hearing at the standard frequencies. If your results show no signs of abnormalities, you will be invited to participate in the second part of the study.

Part two of the study involves testing your hearing at the higher frequencies using the new bone-conduction device and standard headphones. The bone-conduction device consists of a headband and a small metal disk attached to it which will be positioned on your forehead. Just like in a standard hearing test, you will be asked to listen for tones and to press a button to indicate when you have heard them. The quietest sounds you can respond to (thresholds) will be measured, and data will be recorded onto an audiogram sheet. Both parts of the study will take approximately 45 to 60 minutes. The hearing results will be given to you immediately following testing.

In the performance of the tasks and application of the procedures there is a risk that a hearing loss may be detected, in which case these results will be discussed with you and you will be invited to make an appointment at the University of Canterbury Speech and Hearing Clinic for a free diagnostic hearing assessment and consultation at your convenience.

Participation is voluntary and you have the right to withdraw at any stage without penalty. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you. However, once analysis of raw data starts within one month of testing your hearing, it will become increasingly difficult to remove the influence of your data on the results.

The results of the tests you participate in will be used in the current study, and may also be used in future studies within the University of Canterbury. The results of the project may be published, but you may be Monique Howey

assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public without your prior consent. To ensure anonymity and confidentiality, no identifiable information will be used in any reports throughout this study, and only the research team will have access to the information you provide. All data collected will be kept in locked and secure facilities and in password protected electronic form, and will be destroyed after ten years. A thesis is a public document and will be available through the UCLibrary.

Please indicate to the researcher on the consent form if you would like to receive a copy of the summary of results of the project.

The project is being carried out as a requirement for a Master of Audiology degree by Monique Howey under the supervision of Associate Professor Gregory O'Beirne, Dr Melissa Babbage and Mr Philip Bird, who can be contacted at gregory.obeirne@canterbury.ac.nz, melissa.b@dilworth.co.nz and phil.bird@chchorl.co.nz, respectively. They will be pleased to discuss any concerns you may have about participation in the project.

If you have any questions or would like anything to be explained to you in further detail, please do not hesitate to contact the research team. If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050

Free fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, you are asked to please complete the consent form and return it to the researcher, either in person or by sending the consent form to monique.howey@pg.canterbury.ac.nz.

Monique Howey

Appendix 1b. Information sheet for participants undergoing middle ear surgery



Department of Communication Disorders
Email: monique.howey@pg.canterbury.ac.nz
13.06.18

Changes in Extended High Frequency Hearing Impairment Following Middle Ear Surgery

Information Sheet

My name is Monique Howey and I am the primary researcher in a study designed to assess the effect of middle ear surgery on hearing levels in the high-frequency range. Your participation in this study is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part you will receive the standard treatment/care available.

Ear surgery is performed for different reasons but a common reason is to improve hearing. Hearing often improves at the hearing frequencies (pitches) that are tested during a standard hearing test. However, there may be decreases in hearing in the higher frequencies that are not usually tested. This can be due to very subtle trauma to the inner ear during surgery. The inner ear (cochlea) is a very delicate hearing organ and it is possible that it is affected by some surgical trauma, such as vibration from equipment and inflammation during the healing process. When the cochlea is damaged, hearing is generally more easily affected in the higher frequencies. These frequencies are above the frequency levels that we usually test, but the audiology department is able to test these frequencies with special equipment.

Our department is very interested in studying the effect of middle ear surgery on all frequencies of hearing (those that are typically measured and the high frequencies that are not commonly measured). This will give us good information into whether the cochlea is affected after middle ear surgery and also help us plan future treatment to minimize the effect of surgery on the ear.

If you choose to take part in this study, your participation in this project will involve having an extra hearing test (ten minutes) in addition to the standard hearing test that you will be having anyway. This extra hearing test will involve pressing a button in response to ultra-high pitch tones that you hear first through headphones that are placed on your ears, and then through a special device that sits on your forehead and gently vibrates the bone. Data will be recorded by the researcher onto an audiogram sheet, and it is anticipated that testing will take one hour in total.

As a follow-up to this investigation, you will be asked to repeat these hearing tests at your post-operative visits, when you would be having a hearing test anyway. The study will not impact your surgery success in any way, nor will it affect healing.

In the performance of the tasks and application of the procedures there is a risk that a change in your hearing may be detected, in which case these results will be discussed with you and you will be invited to make an appointment at the University of Canterbury Speech and Hearing Clinic for a free diagnostic hearing assessment and consultation at your convenience.

Participation is voluntary and you have the right to withdraw at any stage without penalty or effect on your care after surgery. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you. However, once analysis of raw data starts within one month after testing commences, it will become increasingly difficult to remove the influence of your data on the results.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public without your prior consent. To ensure
Monique Howey

anonymity and confidentiality, no identifiable information will be used in any reports throughout this study, and only the research team will have access to the information you provide. All data collected will be kept in locked and secure facilities and in password protected electronic form, and will be destroyed after ten years. A thesis is a public document and will be available through the UCLibrary.

Please indicate to the researcher on the consent form if you would like to receive a copy of the summary of results of the project.

The project is being carried out as a requirement for a Master of Audiology degree by Monique Howey under the supervision of Associate Professor Gregory O'Beirne, Dr Melissa Babbage and Mr Philip Bird, who can be contacted at gregory.obeirne@canterbury.ac.nz, melissa.b@dilworth.co.nz and phil.bird@chchorl.co.nz, respectively. They will be pleased to discuss any concerns you may have about participation in the project.

If you have any questions or would like anything to be explained to you in further detail, please do not hesitate to contact the research team. If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050

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This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, you are asked to please complete the consent form and return it to the researcher, either in person or by sending the consent form to monique.howey@pg.canterbury.ac.nz.

Appendix 1c. Information sheet for participants from the Babbage (2015) study



Department of Communication Disorders
Email: monique.howey@pg.canterbury.ac.nz
13.06.18

Changes in Extended High Frequency Hearing Impairment Following Middle Ear Surgery

Information Sheet

My name is Monique Howey and I am the primary researcher in a study designed to assess the effect of middle ear surgery on hearing levels in the high-frequency range. Your participation in this study is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part you will receive the standard treatment/care available.

Ear surgery is performed for different reasons but a common reason is to improve hearing. Hearing often improves at the hearing frequencies (pitches) that are tested during a standard hearing test. However, there may be decreases in hearing in the higher frequencies that are not usually tested. This can be due to very subtle trauma to the inner ear during surgery. The inner ear (cochlea) is a very delicate hearing organ and it is possible that it is affected by some surgical trauma, such as vibration from equipment and inflammation during the healing process. When the cochlea is damaged, hearing is generally more easily affected in the higher frequencies. These frequencies are above the frequency levels that we usually test, but the audiology department is able to test these frequencies with special equipment.

Our department is very interested in studying the effect of middle ear surgery on all frequencies of hearing (those that are typically measured and the high frequencies that are not commonly measured). This will give us good information into whether the cochlea is affected after middle ear surgery and also help us plan future treatment to minimize the effect of surgery on the ear.

If you choose to take part in this study, your participation in this project will involve having an extra hearing test (ten minutes) in addition to a standard hearing test, just like when you had your previous ear surgery a few years ago. This extra hearing test will involve pressing a button in response to ultra-high pitch tones that you hear first through headphones that are placed on your ears, and then through a special device that sits on your forehead and gently vibrates the bone. Data will be recorded by the researcher onto an audiogram sheet, and it is anticipated that testing will take one hour in total.

In the performance of the tasks and application of the procedures there is a risk that a change in your hearing may be detected, in which case these results will be discussed with you and you will be invited to make an appointment at the University of Canterbury Speech and Hearing Clinic for a free diagnostic hearing assessment and consultation at your convenience.

Participation is voluntary and you have the right to withdraw at any stage without penalty or effect on your care after surgery. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you. However, once analysis of raw data starts within one month after testing commences, it will become increasingly difficult to remove the influence of your data on the results.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public without your prior consent. To ensure anonymity and confidentiality, no identifiable information will be used in any reports throughout this study, and only the research team will have access to the information you provide. All data collected will be kept

Monique Howey

in locked and secure facilities and in password protected electronic form, and will be destroyed after ten years. A thesis is a public document and will be available through the UCLibrary.

Please indicate to the researcher on the consent form if you would like to receive a copy of the summary of results of the project.

The project is being carried out as a requirement for a Master of Audiology degree by Monique Howey under the supervision of Associate Professor Gregory O'Beirne, Dr Melissa Babbage and Mr Philip Bird, who can be contacted at gregory.obeirne@canterbury.ac.nz, melissa.b@dilworth.co.nz and phil.bird@chchorl.co.nz, respectively. They will be pleased to discuss any concerns you may have about participation in the project.

If you have any questions or would like anything to be explained to you in further detail, please do not hesitate to contact the research team. If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050

Free fax: 0800 2 SUPPORT (0800 2787 7678)

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This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, you are asked to please complete the consent form and return it to the researcher, either in person or by sending the consent form to monique.howey@pg.canterbury.ac.nz.

Appendix 2. Participant consent form



Department of Communication Disorders
Email: monique.howey@pg.canterbury.ac.nz

Changes in Extended High Frequency Hearing Impairment Following Middle Ear Surgery

Consent Form

- ☐ I have been given a full explanation of this project and have had the opportunity to ask questions.
- ☐ I understand what is required of me if I agree to take part in the research.
- ☐ I understand that participation is voluntary and I may withdraw at any time without penalty. Withdrawal of participation will also include the withdrawal of any information I have provided should this remain practically achievable.
- ☐ I understand that any information or opinions I provide will be kept confidential to the researcher and that any published or reported results will not identify the participants. I understand that a thesis is a public document and will be available through the UC Library.
- ☐ I understand that all data collected for the study will be kept in locked and secure facilities and/or in password protected electronic form and will be destroyed after ten years.
- ☐ I understand the risks associated with taking part and how they will be managed.
- ☐ I understand that I can contact the researcher Monique Howey by sending an email to monique.howey@pg.canterbury.ac.nz or supervisors Associate Professor Gregory O'Beirne, Dr Melissa Babbage and Mr Philip Bird by emailing gregory.obeirne@canterbury.ac.nz, melissa.b@dilworth.co.nz or phil.bird@chch.orl.co.nz for further information. If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz)
- ☐ I would like a summary of the results of the project.
- ☐ By signing below, I agree to participate in this research project.

Name: _____ Signed: _____ Date: _____

Email address: _____

Please return the completed consent form back to Monique Howey, either in person or by sending it to the researcher at monique.howey@pg.canterbury.ac.nz.

Thank you for your assistance.

Monique Howey